

# **EPA REG. No 70127-6 Vol. 1**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 17 2003

Dr. Edgar Butts  
Earth BioSciences  
451 Orange St.  
New Haven, CT 06511

Subject: Application for registration of expanded uses for TAEGRO™ containing the active ingredient *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 dated May 3, 2002 (EPA Reg. No. 72098-5)

Dear Dr. Butts:


The amendment referred to above, submitted in connection with registration under FIFRA section 3(c)(7)(A), is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA section 3(c)(5) when the Agency requires all registrants of similar products to submit such data.
2. Submit five (5) copies of your final printed labeling before you release the product for shipment. Final printed labeling means the label or labeling of the product when distributed or sold. Clearly legible reproductions or photo reductions will be accepted for unusual labels, such as those silk-screened directly onto glass or metal containers or large bags or drum labels.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records.

Sincerely,

  
Janet Andersen, Ph.D., Director  
Biopesticides and Pollution  
Prevention Division (7511C)

Enclosure

CONCURRENCES

SYMBOL	7511C	7.511C						
SURNAME	R. Rose	SZUHAY						
DATE	7-17-03	7-17-03						

ENVIRONMENTAL PROTECTION AGENCY

1 CFR Part 180

[OPP-2003-0059; FRL-7309-8]

*italics*

**Bacillus subtilis var. amyloliquefaciens strain FZB24; Exemption from the Requirement of a Tolerance**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 on all agricultural commodities when applied/used in accordance with good agricultural use practices for plant strengthening, growth enhancement, and plant disease suppression. Earth BioSciences submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

**DATES:** This regulation is effective [insert date of publication in the Federal Register]. Objections and requests for hearings, identified by docket ID number OPP-2003-0059, must be received on or before [insert date 60 days after date of publication in the Federal Register].

**ADDRESSES:** Written objections and hearing requests may be submitted by mail or through hand delivery/courier. Follow the detailed instructions as provided in Unit IX. of the SUPPLEMENTARY INFORMATION.

**FOR FURTHER INFORMATION CONTACT:** Robyn Rose, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9581; e-mail address: rose.robyn@epa.gov.

**SUPPLEMENTARY INFORMATION:**

03P 2806							
CONCURRENCES							
SYMBOL	7104T	7104T	7511C	7511C	7511C		
SERIAL	TRAVELER	Q.B. Rose	R. Rose	S. Chav	Amherst		
DATE	6-6-03	6/6/2003	6/12/03	6-2-03	6/20/03		3

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### **SUPPLEMENTARY INFORMATION:**

#### **I. General Information**

##### **A. Does this Action Apply to Me?**

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)

- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)
- Antimicrobial pesticides (NAICS 32561)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Copies of this Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2003-0059. The official public docket is intended to serve as a repository for materials (i.e., documents and other information) submitted to the Agency in connection with this action and/or relied upon by the Agency in taking this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805. To the extent that a particular document is not located in the official public docket, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>. A frequently updated electronic version of 40 CFR part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select "search," then key in the appropriate docket ID number.

## II. Background and Statutory Findings

In the *Federal Register* of October 22, 2002 (67 FR 32231) (FRL-7275-7), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a(d), as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide tolerance petition (PP 2F06453) by Earth BioSciences, 451 Orange St, New Haven, CT 06511. This notice included a summary of the petition prepared by the petitioner Earth BioSciences. There were no comments received in response to the Notice of Filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

Section 408(c)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of the FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of the FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ." Additionally, section 408(b)(2)(D) of the FFDCA requires that the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

## III. Toxicological Profile

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness, and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Earth BioSciences, formerly Taensa, Inc., conducted the toxicology studies required under section 408(d)(2)(A) of the FFDCA to support

its petition for an exemption from the requirement of tolerance for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. As illustrated below, the studies conducted indicate a low mammalian toxicity for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. In addition, no pathogenicity or infectivity was observed in any of the tests conducted with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. All toxicology data generated by Earth BioSciences have been reviewed by the Biopesticides and Pollution Prevention Division ("BPPD").

Toxicology data in support of the exemption from the requirement of a tolerance for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 included studies with spores (technical) and with the formulated product (water dispersible powder) as follows:

1. *Acute toxicity and/or pathogenicity—i. Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 Spores (Technical):

- *Acute oral toxicity/pathogenicity in rats.* "... does not appear to be toxic and/or pathogenic in rats when dosed at  $1.3 \times 10^8$  cfu." BPPD Review of Product Chemistry and Toxicity/Pathogenicity Data Submitted by Taensa, Inc., for the Registration of TAE-022 and TAE-022 WDG, which contains *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 (Submission No.: S559221; DP Barcode: 254584; Master Record Identification (MRID) No's.: 447581-01 through 447581-20) (hereinafter referred to as "BPPD Review - December 20, 1999").

- *Acute dermal toxicity/pathogenicity in rabbits.* "The severity of irritation persisted 72 hours, and slight irritation persisted for 10 days, and all resolved by day 11. No deaths observed. The acute lethal dose ( $LD_{50}$ ) is greater than 2,000 mg/kg ... Dermal Toxicity = Toxicity III." (BPPD Review - December 20, 1999).

- *Acute inhalation toxicity in rats.* "The inhalation  $LC_{50}$  for males, females, and combined was  $> 0.93$  mg/L. Toxicity Category III." (Submission No.: S616797; DP Barcode: 283473; MRID No's.: 456725-01 and 456725-02) (hereinafter referred to as "BPPD Review - April 25, 2002")

- *Acute pulmonary toxicity/pathogenicity in rats.* "... does not appear to be toxic and/or pathogenic in rats, when dosed at  $1.3 \times 10^8$  cfu/animal. No total clearance is seen from the lungs of treated test animals ... showed a distinct pattern of clearance from kidney, liver, and spleen." (BPPD Review - December 20, 1999).

- *Acute intravenous toxicity/pathogenicity in rats.* "... does not appear to be toxic and/or pathogenic in rats, when dosed at  $1.7 \times 10^8$  cfu/animal." (BPPD Review - December 20, 1999).

- *Primary eye irritation.* "... showed no signs of persistent irritation into day 21, when dosed at  $4.7 \times 10^{10}$  cfu/right eye/animal." (BPPD Review - December 20, 1999.) The December 20, 1999 BPPD

review indicated Toxicity Category I, but was amended in a March 7, 2000 review to Toxicity Category II based on a comparison of test animals showing similar recovery trends and leading to reversibility within 21 days. Addendum to Toxicity Category for TAE-022, which contains *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 (Submission No.: S559221; DP Barcode: 254584; MRID No.: 447581-14).

- *Primary dermal irritation.* "... severity of irritations persisted >72 hours, but resolved by day 11. Dermal irritation = Toxicity II." (BPPD Review - December 20, 1999).

- *Hypersensitivity testing.* "Based on the submitted data ... does not appear to be a sensitizer when dosed at  $3.6 \times 10^{10}$  cfu." (BPPD Review - December 20, 1999).

- *Hypersensitivity incident reporting.* "No recorded or reported hypersensitivity reaction ... based on handling MCPA in lab control setting, equating to 55 person years. ..." (BPPD Review - December 20, 1999).

- *Immune response.* "There is no information to suggest that *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 has an effect on the immune system. The submitted toxicity/pathogenicity studies in rodents indicated that following several routes of exposure, the immune system is still intact and able to process and clear the active ingredient." (BPPD Review - December 20, 1999).

- *Potential health effects.* "Based on information given, there are no apparent negative effects ... Cited literature on *B. subtilis* indicate and/or support the development as a biological control. ..." (BPPD Review - December 20, 1999).

- *Growth parameters.* "... is shown to grow at all tested temperatures (e.g., 30, 34, 37, and 50 °C). The enumeration shows a low  $4.2 \times 10^{+1}$  cfu/g at 37 °C to a high  $6.0 \times 10^{11}$  cfu/g at 34 °C." (BPPD Review - December 20, 1999).

ii. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 WDG (Formulation):

- *Acute oral LD<sub>50</sub> toxicity in rats.* "Toxic/limit dose ... is greater than 2.8 g/kg body weight ( $6.7 \times 10^{10}$  cfu/kg). ... Toxicity Category III." (BPPD Review - December 20, 1999).

- *Acute dermal LD<sub>50</sub> toxicity in rats.* "The severity of irritation persisted >72 hours, but resolved by day 11. No deaths observed. The acute dose (LD<sub>50</sub>) is greater than 2,000 mg/kg. ... Dermal irritation = Toxicity Category II; Dermal Toxicity = Toxicity Category III." (BPPD Review - December 20, 1999).

- *Acute inhalation lethal concentration (LC<sub>50</sub>) toxicity in rats (Formulation).* "... an acute inhalation medium (LC<sub>50</sub>) in male and



female rats is greater than 0.93 mg/L . . . Toxicity Category III." (BPPD Review - April 25, 2002)

- *Primary eye irritation.* "No corneal opacity, and no signs of irritation by day 7, when dosed . . . at  $3.6 \times 10^{10}$  cfu/right eye/animal. . . . Toxicity Category III." (BPPD Review - December 20, 1999).
- *Hypersensitivity.* "Not a sensitizer when dosed at  $3.6 \times 10^{10}$  cfu. No hypersensitivity incidents have been reported." (BPPD Review - December 20, 1999).

Based on the data generated in accordance with the Tier I data requirements set forth in 40 CFR 158.740(c), the Tier II and Tier III data requirements were not triggered and, therefore, not required in connection with this action.

#### IV. Aggregate Exposures

In examining aggregate exposure, section 408 of the FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

##### A. Dietary Exposure

*Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is a naturally-occurring microorganism and widespread in the environment. The low toxicity and non-pathogenicity/infectivity of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is demonstrated by the data summarized in this action. The end-use (formulated) product will be applied to all agricultural commodities as a seed treatment and via incorporation, drenching, spraying, dipping, chemigation and hydroponics.

1. *Food.* While the proposed use pattern may result in dietary exposure with possible residues on all agricultural commodities, negligible risk is expected for the general population, as well as for infants and children. Submitted acute toxicology tests (MRID Numbers 447581-08, 447581-09, 447581-10, 447581-11, 447581-12, 447581-13, 447581-14, 447581-16, and 456725-02) demonstrate that based upon the use sites, use patterns, application method, use rates, low exposure, and minimal risk of toxicity, the potential risks from dietary exposure for both the general population and infants and children are considered low.

2. *Drinking water exposure.* Although *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 spores may be found naturally in water, it is not known as an aquatic bacterium, and therefore is not expected to proliferate in aquatic habitats. (Earth BioSciences petition from the requirement of a tolerance for *Bacillus subtilis* var. *amyloliquefaciens*

strain FZB24, dated May 3, 2002.) In addition, the potential for transfer of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 to surface or ground water during run-off associated with intended use applications is considered minimal to non-existent, due in part to its percolation through and resulting capture in soil. Most importantly, though, the risk from consumption of drinking water containing *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is considered minimal as there is no evidence of adverse effects from oral, dermal, or inhalation exposure to this microbial agent. (See Unit III.) Accordingly, it is not considered to be a risk to drinking water.

#### B. Other Non-Occupational Exposure

Based on the proposed use patterns, the potential of non-dietary exposures to *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 pesticide residues for the general population, including infants and children, is unlikely. Accordingly, the Agency believes that the potential aggregate non-occupational exposure, derived from dermal and inhalation exposure through the application of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24, should fall well below the currently tested microbial safety levels. (MRID Numbers 447581-10, 447581-11, 447581-12, and 456725-02).

1. *Dermal exposure.* Dermal exposure via the skin is a potential route of exposure resulting from applications of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. Unbroken skin is a natural barrier to microbial invasion of the human body. Dermal absorption could occur only if the skin were cut, if the microbe were a pathogen equipped with mechanisms for entry through or infection of the skin, or if metabolites were produced that could be dermally absorbed. Acute dermal toxicity/pathogenicity data resulted in irritation that persisted 72 hours, and slight irritation persisted for 10 days, and all resolved by day 11. No deaths were observed. The acute lethal dose (LD<sub>50</sub>) is greater than 2,000 mg/kg. (BPPD Review - December 20, 1999). Accordingly, the risks anticipated for this route of exposure are considered minimal.

2. *Inhalation exposure.* Inhalation would be an additional potential route of exposure resulting from applications of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. However, because the pulmonary study showed no adverse effects (MRID Numbers 447581-12 and 456725-02) the risks anticipated for this route of exposure are considered minimal.

#### V. Cumulative Effects

The Agency has considered available information on the cumulative effects of such residues and other substances that have a common mechanism of toxicity. These considerations included the cumulative effects on infants and children of such residues and other substances with a common mechanism of toxicity. Because there is no indication of mammalian toxicity to *Bacillus subtilis* var.

*amyloliquefaciens* strain FZB24, the Agency is confident that there will not be cumulative effects from the residues of this product on all agricultural commodities. (See Unit III.)

## VI. Determination of Safety for U.S. Population, Infants and Children

1. *U.S. population.* *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is a naturally occurring microorganism and is widespread in the environment. Based on the very low levels of mammalian toxicity associated with *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24, which is demonstrated by the data summarized above, and the history of safe use of *B. subtilis*, the Agency has concluded that there is a reasonable certainty that no harm will result from aggregate exposure to residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 to the U.S. population. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. Accordingly, exempting *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 from the requirement of a tolerance should be considered safe and pose no significant risk.

*Bacillus subtilis* var. *amyloliquefaciens*

2. *Infants and children.* FFDCA section 408(b)(2)(C) provides that EPA shall apply an additional tenfold margin of exposure (safety) for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are incorporated into EPA risk assessments either directly through the use of a margin of exposure analysis or by using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. Here, EPA concludes that the toxicity and exposure data are sufficiently complete to adequately address the potential for additional sensitivity of infants and children to residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 and that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 residues. Also, for food use of microbial pesticides, the acute toxicity/pathogenicity studies have allowed for the conclusion that an exemption from the requirement of a tolerance for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is appropriate and adequate to protect human health, including that of infants and children.

## VII. Other Considerations

### A. Endocrine Disruptors

EPA is required under section 408(p) of the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its



Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the screening program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on available data, no endocrine system-related effects have been identified with consumption of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. It is a naturally occurring bacteria that is widespread in the environment. To date, there is no evidence to suggest that *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 affects the immune system, functions in a manner similar to any known hormone, or that it acts as an endocrine disruptor.

#### *B. Analytical Method*

The Agency proposes to establish an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24's lack of mammalian toxicity. For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purpose for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

#### *C. Codex Maximum Residue Level*

There are no Codex maximum residue levels established for residues of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24.

### **VIII. Objections and Hearing Requests**

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA provides essentially the same process for persons to "object" to a regulation for an exemption

from the requirement of a tolerance issued by EPA under new section 408(d) of the FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. However, the period for filing objections is now 60 days, rather than 30 days.

*A. What Do I Need to Do to File an Objection or Request a Hearing?*

You must file your written objections and hearing requests with the Hearing Clerk in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP-2003-0059 in the subject line on the first page of your submission. All objections and hearing requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before *[insert date 60 days after date of publication in the Federal Register]*.

1. *Filing the request.* Your objections must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. You may also deliver your request to the Office of the Hearing Clerk in Rm.104, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (703) 603-0061.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it "Tolerance Petition Fees."

EPA is authorized to waive any fee requirement "when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection." For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at

tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2003-0059, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.1. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

#### *B. When Will the Agency Grant a Request for a Hearing?*

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

### **IX. Statutory and Executive Order Reviews**

This final rule establishes an exemption from the tolerance requirement for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 under section 408(d) of the FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355.

May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of the FFDCA, such as the exemption from the tolerance requirement in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure "meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications." "Policies that have federalism implications" is defined in the Executive Order to include regulations that have "substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government." This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of the FFDCA. For these same reasons, the Agency has determined that this rule does not have any "tribal implications" as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure "meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications." "Policies that have tribal implications" is defined in the Executive Order to include regulations that have "substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian

tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

#### **X. Congressional Review Act**

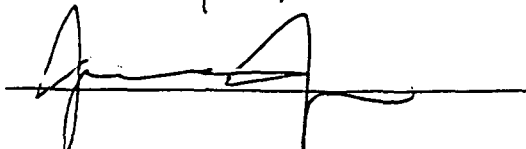
The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a "major rule" as defined by 5 U.S.C. 804(2).



**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure,  
Agricultural commodities, Pesticides and pests, Reporting and  
recordkeeping requirements.

Dated: 6/20/03

A handwritten signature in black ink, appearing to be 'J. A.', written over a horizontal line.

*Director, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**ART 180—[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.1243 is added to subpart D to read as follows:

**§ 180.1243     *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24;  
exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance for residues of the *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 in or on all agricultural commodities when applied/used in accordance with label directions.

[FR Doc. 03-???? Filed ??-??-03; 8:45 am]

BILLING CODE 6560-50-S



451 Orange Street, New Haven, CT 06511 U.S.A.

Telephone: 203-562-7773

Fax: 203-562-2207

e-mail: [erbiierb@localnet.com](mailto:erbiierb@localnet.com)

September 23, 2002

Dr. Robert Torla  
Biopesticides and Pollution Prevention Division  
Environmental Protection Agency  
401 M Street SW  
Washington, DC 20460

**Subject: Taensa, Inc.  
Change of Company Name and Address**

Dear Bob:

In order to better reflect its direction and mission, Taensa, Inc. has changed its name. We have also relocated. The details are as follows:

Earth BioSciences Inc.  
451 Orange Street  
New Haven, CT 06511

Telephone: 203-562-7773  
Fax: 203-562-2207  
e-mail: [erbiierb@localnet.com](mailto:erbiierb@localnet.com)

Per our discussion, this notification to you is all that I need to do to effect the changes. Also, it is my understanding that our company number will remain 72098.

Should you have any questions regarding this application, please contact me. Thank you for your continued assistance.

Sincerely,

A handwritten signature in cursive script, appearing to read "EQ", is written above the printed name.

Edgar R. Butts, Ph.D.  
Chief Scientific Officer

cc: Dr. Phil Hutton  
Dr. Sherry Reilly  
Ms. Robyn Rose  
Mr. Leonard Cole

# taensa<sup>INC</sup>

*the biocontrol company*

26 Sherman Court, P.O. Box 764, Fairfield, CT 06430 U.S.A.

Telephone: 203-256-0460

Fax: 203-256-0464

e-mail: [erb@taensa.com](mailto:erb@taensa.com)

Via U.S. Postal Service - Certified Mail (7000 0520 0021 5244 1210) - Return Receipt Requested

May 3, 2002

Environmental Protection Agency  
Headquarters Accounting Operations Branch  
Office of Pesticide Programs (Tolerance Fees)  
P.O. Box 360277M  
Pittsburgh, PA 15251

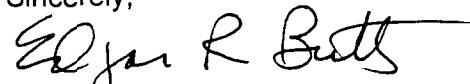
**Subject:** Tolerance Petition Fee  
Petition for an Exemption from the Requirement of a Tolerance for *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 in or on All Raw Agricultural Commodities When Used for Plant Strengthening, Growth Enhancement and/or Suppression of Certain Diseases in Accordance with Good Agricultural Practices

To Whom It May Concern:

Enclosed is a bank check for \$14,325 drawn to the order of the Environmental Protection Agency. The fee is for the required tolerance fee for the subject petition.

If you have any questions, please advise.

Sincerely,



Edgar R. Butts, Ph.D.  
Chief Executive Officer

Enclosure



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Dr. Edgar R. Butts, Ph.D  
Taensa Inc.  
26 Sherman Ct.  
Fairfield, Ct 06430

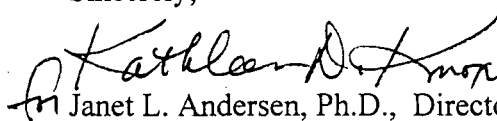
Subject: Amendment to Toxicity Category for the primary eye irritation study submitted in support of TAE-022 Technical registration (EPA Registration No. 72098-6; Submission No. S559221; DP Barcode No. 254584; MRID No. 447581-14).

Dear Dr. Butts:

The Agency reevaluated the primary eye irritation studies Taensa Inc. submitted in support of the TAE-022 Technical (active ingredient *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24; EPA Reg. No. 72098-6) registration. The amended review of MRID No. 447581-14 concluded that the initial finding of Toxicity Category I should be changed to Toxicity Category II. The "Warning" precautionary statement currently printed on the label is acceptable.

For further information, please contact Robyn Rose, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency 1200 Pennsylvania Ave, NW Washington, D.C. 20460; Phone (703) 308-9581 (or 308-8712); Fax (703) 308-7026; or e-mail: [rose.robyn@epa.gov](mailto:rose.robyn@epa.gov).

Sincerely,

  
Janet L. Andersen, Ph.D., Director  
Biopesticides and Pollution  
Prevention Division (7511C)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

Dr. Edgar R. Butts, Ph.D  
Taensa Inc.  
26 Sherman Ct.  
Fairfield, Ct 06430

Dear Dr. Butts:

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> customer service line added

Sincerely,

Janet L. Andersen, Ph.D., Director  
Biopesticides and Pollution  
Prevention Division (7511C)

CONCURRENCES							
SYMBOL	7511C	7511C					
SURNAME	R. Rose	Butts	KNOX				
DATE	3/9/00	3/20/00	3/21/00				

Dr. Edgar R. Butts, Ph.D  
Taensa Inc.  
26 Sherman Ct.  
Fairfield, Ct 06430

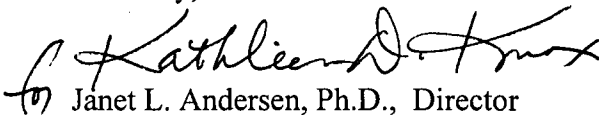
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Sincerely,

  
(7) Janet L. Andersen, Ph.D., Director  
Biopesticides and Pollution  
Prevention Division (7511C)





U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Biopesticides and Pollution Prevention Division  
(7501W) 401 M St., S.W.  
Washington, D.C. 20460

EPA Reg.  
Number:

72098-6

Date of Issuance:

JAN 20 2000

NOTICE OF PESTICIDE:

X Registration

\_\_\_\_ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

TAE-Technical

Name and Address of Registrant (include ZIP Code):

Taensa Inc  
26 Sherman Ct  
P.O. Box 764  
Fairfield, CT 06430

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If EPA determines at any time, that additional data are required to maintain in effect an existing registration, the Agency will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms and conditions:

1. Submit five(5) copies of the revised final printed labeling including the EPA Registration Number and Establishment Number before you release the product for shipment. Refer to the A-79 enclosure for a further description of final printed labeling.

A stamped copy of the label is enclosed for your records.

Sincerely,

Janet L. Andersen, Ph.D.  
Director  
Biopesticides and Pollution  
Prevention Division (7511C)

Signature of Approving Official:

Date:

1-20-00



# TAE-022 TECHNICAL

## FOR MANUFACTURING PURPOSES ONLY

	% w/w
<b>ACTIVE INGREDIENT</b> – <i>Bacillus subtilis</i> var. <i>amyloliquefaciens</i> Strain FZB24* .....	73.3%
<b>OTHER INGREDIENTS</b> .....	26.7%
Total	100.0%

\* Contains  $5.0 \times 10^{11}$  Colony Forming Units ("CFU")/gram.

### KEEP OUT OF REACH OF CHILDREN

## WARNING

### PRECAUTIONARY STATEMENTS

#### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

## WARNING

Causes substantial but temporary eye injury. Do not get in eyes. Wear protective eyewear (goggles, face shield, or safety glasses). Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling.

### FIRST AID

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

**IF SWALLOWED:** Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available, by administering syrup of ipecac. If a person is unconscious, do not give anything by mouth and do not induce vomiting.

**IF ON SKIN OR CLOTHING:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED** - Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth to mouth. Get medical attention.

### EMERGENCY INFORMATION

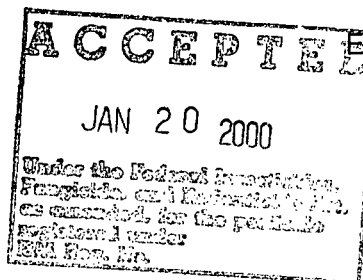
For spill, leak, fire, exposure, or accident call CHEMTREC at 1-800-424-9300.

### ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Net Contents \_\_\_\_\_

Taensa, Inc.  
26 Sherman Court  
P.O. Box 764  
Fairfield, CT 06430 U.S.A.



EPA Establishment Number  
EPA Registration Number: 72098-1  
Made in U.S.A.  
Revision: 990208

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into product for the following use:

- For plant strengthening, growth enhancement and suppression of certain diseases

This product may be used to formulate products for any additional use(s) not listed on the TAE-022 Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

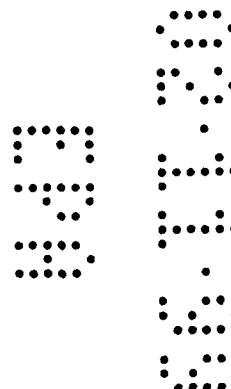
**STORAGE:** TAE-022 consists of living microbes. Store in a cool dry place. Do not freeze or expose to temperatures above 80° F. Opened packages should be closed tightly and stored in a cool dry place and used within one month.

**PESTICIDE DISPOSAL:** Unused TAE-022 Technical and wastes resulting from the use of this product may be disposed of in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**CONTAINER DISPOSAL:** Dispose of empty bag in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

## CONDITIONS OF SALE

Taensa, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.



MEMORANDUM

SUBJECT: Consideration of unconditional registration of the new microbial pesticide chemical *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 (EPA File Symbol 72098-L; PC Code 006480). This pesticide will be used to aid in the control of fungi on indoor and greenhouse growing ornamentals, shrubs, shade and forest trees.

..... DECISION MEMORANDUM .....

FROM: Janet L. Andersen, Director  
Biopesticides and Pollution Prevention Division (7511C)

TO: Susan Hazen, Acting Deputy Director  
Office of Pesticide Programs

ISSUE

Should the Agency grant unconditional registration under Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 (PC Code 006480)? This compound will be used to aid in the control of fungi on non-food crops raised in greenhouses or indoors.

CONCLUSION


All data requirements for granting this registration under FIFRA Section 3(c)(5) have been fulfilled. The technical compound TAE-022 Technical (EPA File Symbol 72098-A) contains 73.3% *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 as an active ingredient. The end-use product TAE-022 WDG (EPA File Symbol 72098-L) contains 24.5% *Bacillus*

CONCURRENCES							
SYMBOL	7511C	7511C					
SURNAME	R. Haze	H. Haze	K. NOX				
DATE	1/10/00	1/12/00	1/14/00				

## MEMORANDUM

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Biopesticides and Pollution Prevention Division (7511C)

TO: Susan Hazen, Acting Deputy Director  
Office of Pesticide Programs

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## CONCLUSION

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*Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is a naturally-occurring bacteria found in soil and leaf litter. No toxicological end-point of concern was identified. The health risk is expected to be minimal for oral, dermal, and inhalation exposure routes. The exposure and risk to non-target organisms, including fish, birds, and insects, is expected to be minimal because the product is not to be used outdoors. A determination has been made that because of the low toxicity and the limited exposure to this product, no unreasonable adverse effects will result from the use of this compound when label instructions are followed. Furthermore, BPPD has not identified any subchronic, chronic, immune, endocrine, or nondietary exposure issues as they may affect children and the general U.S. population.

Refer to the Registration Eligibility Decision Document for *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 for more details.

#### OFFICE DIRECTOR'S CONCURRENCE

The Biopesticides and Pollution Prevention Division recommends that *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 be unconditionally registered under Section 3(c)(5) of FIFRA.

Concurrence:

Susan B. Hyatt

Non-Concurrence:

Date:

1/20/2000



## BIOPESTICIDE FACT SHEET

Active Ingredient Name:      *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24

OPP Chemical Code:              006480

### SUMMARY

*Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is a naturally occurring bacterium that can be used to control various fungal diseases in non-food crops. It is approved only for use in greenhouses and indoors. This bacteria is not expected to have adverse effects on humans or the environment.

### I. DESCRIPTION OF THE ACTIVE INGREDIENT

*Bacillus subtilis* is a widespread bacteria found in soil and leaf litter that can be readily grown in the laboratory. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is used for plant strengthening, enhancing, growth, increasing yields, and for suppressing selected soil-born fungal diseases such as *Rhizoctonia* and *Fusarium*.

### II. USE SITES, TARGET PESTS, AND APPLICATION METHODS

Use Sites:      *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is approved for use only in greenhouses and other indoor sites. It can be used on a wide variety of ornamentals, shrubs, shade and forest tree seedlings.

Target Pests:      Selected soil-born fungal diseases such as *Rhizoctonia* and *Fusarium*

#### Application

Methods:      *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is sold as a water dispersible granule. It can be drenched onto soil, cutting or root dips, or as a dip

or drench for transplants including plugs. When drenching, apply to seedlings or to newly rooted cuttings. Cutting and root dips should be placed in the suspension for five to ten minutes allowing time to penetrate the rootzone. Ornamentals should receive at least one follow-up drench treatment two to three weeks following initial treatment. Transplants and plugs root system should be dipped or drenched prior to planting.

### III. ASSESSING RISKS TO HUMAN HEALTH

No harmful health effects to humans are expected from use of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. *B. subtilis* is not normally a human pathogen, but has been isolated from human infections.

However, such occurrences are typically limited to patients with compromised immune systems because of some other condition or disease. *Bacillus subtilis* naturally exists in the environment, and people are normally exposed to it. It is unlikely that the limited uses would noticeably increase human exposure.

Whether or not a substance poses a risk to humans or other organisms depends on two factors: how toxic the substance is, and how much of it an organism is exposed to. Therefore, the EPA considers toxicity data and exposure data in determining whether to approve a pesticide for use.

### IV. ASSESSING RISKS TO THE ENVIRONMENT

The indoor and greenhouse use of *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 is not likely to substantially increase environmental exposure or pose a risk to any organisms except target fungi. *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 occurs in many soil types. No adverse effects on the environment are expected, and none have been reported.

### V. REGULATORY INFORMATION

Taensa Inc. submitted an application February 8, 1999 for registration of TAE-022 Technical and TAE-022 WDG; active ingredient *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24. The product was registered January, 2000.

### VI. PRODUCER INFORMATION

MANUFACTURER :	Taensa Inc.
UNITED STATES AGENT :	Edgar R. Butts, Ph.D. 26 Sherman Ct. P.O. Box 764 Fairfield, CT 06430

## **VII. FOR FURTHER INFORMATION, CONTACT:**

Robyn I. Rose  
Regulatory Action Leader  
Biopesticides and Pollution  
Prevention Division (7511C)  
Office of Pesticide Programs  
Environmental Protection Agency  
1200 Pennsylvania Ave, NW  
Washington, D.C. 20460  
Phone (703) 308-9581 (or 308-8712)  
Fax (703) 308-7026  
e-mail: [rose.robyn@epa.gov](mailto:rose.robyn@epa.gov)

EPA's biopesticides web site is at <http://www.epa.gov/pesticides/biopesticides>.

DISCLAIMER: The information in this Biopesticide Fact Sheet is a summary only. Contact the Regulatory Action Leader or the web site listed above for further information.



\*\*\*\*\*  
NEW CHEMICAL/FIRST FOOD USE SCREEN  
\*\*\*\*\*

1. FILE SYMBOL/REG NO (ISB) 72098-A
2. TOLERANCE PETITION NO. (RSB) 014
3. CHEMICAL NAME (RSB) Bacillus subtilis var. amyloliquefaciens Strain FZB24
4. PESTICIDE CHEMICAL CODE (RSB) 006480
5. PRODUCT NAME (ISB) TAB-022 WDG
6. PM (ISB) \_\_\_\_\_ 7. PM TEAM REVIEWER (PM) Robyn Rose
8. DATE OF RECEIPT (ISB) \_\_\_\_\_
9. USE PATTERN (PM) \_\_\_\_\_
10. DATE OF TRANSMISSION TO PM (ISB) \_\_\_\_\_  
(EPA Receipt Date plus 3 days)
11. DATE OF TRANSMISSION TO HED/EFED/RSB (PM) \_\_\_\_\_  
(PM Receipt Date plus 5 days)
12. HED/EFED/RSB DUE DATE FOR COMPLETION OF SCREEN \_\_\_\_\_  
(HED/EFED Receipt Date plus 10 days)
13. HED/EFED/RSB REVIEWERS:
- HED: \_\_\_\_\_ EFED: Microbial Pesticides Branch/ Ecological Effects
- TB \_\_\_\_\_ ~~EEB~~ Mike Mendelsohn
- DEB \_\_\_\_\_ EFGWB \_\_\_\_\_
- OREB \_\_\_\_\_
- RD/RSB \_\_\_\_\_
14. HED/EFED/RSB COMPLETION DATE (HED) \_\_\_\_\_ (EFED) \_\_\_\_\_ (RSB) \_\_\_\_\_
15. SUBMISSION BARCODE (PM) \_\_\_\_\_

REGISTRANT PHONE CONTACT INFORMATION (PM)

DATE OF CONTACT \_\_\_\_\_

PERSON CONTACTED \_\_\_\_\_

TITLE \_\_\_\_\_

DECISION & COMMENTS \_\_\_\_\_

STATUS OF PACKAGE

Mike Mendelsohn 4/12/99

- ☒ PASSED  
SCREEN Eco Effects
- ☐ FAILED  
SCREEN  
(Documentation attached)



Avian Oral Tox/Path m Quail	447581-21
21 Day Daphnia Tox/Path	447581-22
Trout Tox/Path	447581-23
Honey Bee Larvae Dietory	447581-24
Honey Bee Adult Dietory	447581-25
Earthworm Toxicity	447581-26
Algae Growth Inhibition	447581-27

## DOCUMENTS BEING SUBMITTED IN SUPPORT OF THE SUBJECT APPLICATIONS

### 1. TAE-022 Technical (For Manufacturing Purposes)

Five (5) copies of the proposed labeling, three (3) copies of supporting data and one (1) copy each of the following are attached in support of the registration of TAE-022 Technical:

- Application for Pesticide - Registration (Form 8570-1)
- Confidential Statement of Formula (Form 8570-4)
- Certification with Respect to Citation of Data (Form 8570-34)
- Data Matrix (Form 8570-35) – Agency Internal Use Copy
- Data Matrix (Form 8570-35) – Public File Copy

### 2. TAE-022 WDG

Five (5) copies of the proposed labeling and one (1) copy each of the following are attached in support of the registration of TAE-022 WDG:

- Application for Pesticide - Registration (Form 8570-1)
- Confidential Statement of Formula (Form 8570-4)
- Certification with Respect to Citation of Data (Form 8570-34)
- Data Matrix (Form 8570-35) – Agency Internal Use Copy
- Data Matrix (Form 8570-35) – Public File Copy

Data supporting the TAE-022 registration are being submitted with the TAE-022 TECHNICAL application.

Taensa appreciates the purpose of the new data matrix forms, but has prepared a "Detailed Listing of Data Submitted and Requests for Waivers to Support Application for Registration of TAE-022 Containing the New Active Ingredient *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 – February 8, 1999." The purpose of this document is to provide the reviewer with a complete compilation of studies submitted and requests for waivers for those studies not submitted to support registration of TAE-022.

### SUPPORT OF APPLICATION FOR REGISTRATION

Taensa will support its application with the data being submitted by Taensa and on its behalf, and with requests for waivers.

Should you have any questions regarding this application, please contact me. Thank you for your continued assistance.

Sincerely,



Edgar R. Butts, Ph.D.  
President and Chief Executive Officer

Enclosures

DETAILED LISTING OF DATA SUBMITTED AND REQUESTS FOR WAIVERS  
TO SUPPORT APPLICATION FOR REGISTRATION  
OF  
*BACILLUS SUBTILIS* VAR. *AMYLOLIQUEFACIENS* STRAIN FZB24  
February 8, 1999

PRODUCT CHEMISTRY

151A-10 Product Identity and Disclosure of Ingredients

- 44758101 Document 1 Product Identity and Disclosure of Ingredients – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. Data Requirement: 152A-10. Edgar R. Butts, Ph.D., Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 3, 1999. 35 Pages.

151A-11 Beginning Materials and Manufacturing Process

- 44758102 Document 2 Beginning Materials and Manufacturing Process – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. Data Requirement: 151A-11. Ulrich Korn, Ph.D. FZB Biotechnik GmbH, Glienicker Weg 185, D-12489 Berlin, GERMANY. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 5, 1999. 26 Pages.

151A-12 Discussion of Formation of Unintentional Ingredients

- 44758103 Document 3 Discussion of Formation of Unintentional Ingredients – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. Data Requirement: 151A-12. Dr. Ralph Freudenthal, Ph.D., Consultant – Toxicology and Regulatory Affairs, 8737 Estate Drive, West Palm Beach, FL 33411. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 21, 1999. 4 Pages.

151A-13 Analysis of Samples

- 44758104 Document 4 Lot Analysis of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24. Data Requirement: 151A-13 (885.1400). Bruce A. Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L03743 SN23. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 19 Pages.

151A-15      Certification of Limits -

- 44758105** Document 5      Certification of Limits. Data Requirement: 151A-15. Edgar R. Butts, Ph.D., Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 5, 1999. 10 Pages.

151A-16      Physical/Chemical Properties - Technical

- 44758106** Document 6      Determination of Color, Physical State, Odor, pH and Density of *Bacillus subtilis* var. *amyloliquefaciens*. Data Requirement: 151A-16 (Color 830.6302, Physical State 830.6303, Odor 830.6304, pH 830.7000, Density 830.7300). Ronda Jacobs and Willard B. Nixon, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 10, 1998. 22 Pages.

151A-16      Physical/Chemical Properties - "WDG" End-Use Product

- 44758107** Document 7      Determination of Color, Physical State, Odor, pH and Density of *Bacillus subtilis* var. *amyloliquefaciens* "WDG" End-Use Product. Data Requirement: 151A-16 (Color 830.6302, Physical State 830.6303, Odor 830.6304, pH 830.7000, Density 830.7300). Ronda Jacobs and Willard B. Nixon, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 10, 1998. 20 Pages.

151A-16      Physical/Chemical Properties - Corrosion Characteristics -  
"WDG" End-Use Product

This study is underway and will be submitted as soon as complete.

## TOXICOLOGY

### 152A-10 Acute Oral Toxicity/Pathogenicity - Technical

**44758108** Document 8 Toxicity/Pathogenicity Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, Following Acute Oral Challenge in Rats. Data Requirement: 152A-10 (885.3050). Kelly A. Harrington, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN2. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 123 Pages.

### 152A-10 Acute Oral Toxicity - "WDG" End-Use Product

**44758109** Document 9 Acute Toxicity/Limit Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, WDG End Use Product, Following Acute Oral Challenge in Rats. Data Requirement: 152A-10 (870.1100). Bruce Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN8. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 29 Pages.

### 152A-11 Acute Dermal Toxicity/Pathogenicity - Technical

**44758110** Document 10 Acute Dermal Toxicity/Pathology Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, in Rabbits. Data Requirement: 152A-11 (885.3100). John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN5. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 28 Pages.

**152A-11      Acute Dermal Toxicity/Pathogenicity – “WDG” End-Use Product**

**44758111**    Document 11    Acute Dermal Toxicity/Pathology Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, WDG End Use Product in Rabbits. Data Requirement: 152A-11 (885.3100). John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN10. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 28 Pages.

**152A-12      Acute Pulmonary Toxicity/Pathogenicity - Technical**

**44758112**    Document 12    Toxicity/Pathogenicity Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, Following Acute Intratracheal Challenge in Rats. Data Requirement: 152A-12 (885.3150). Kelly A. Harrington, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN3. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 133 Pages.

**152A-12      Acute Inhalation Toxicity – “WDG” End-Use Product**

This study is underway and will be submitted as soon as complete.

**152A-13      Acute Intravenous Toxicity/Pathogenicity - Technical**

**44758113**    Document 13    Toxicity/Pathogenicity Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, Following Acute Intravenous Challenge in Rats. Data Requirement: 152A-13 (885.3200). Bruce A. Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN4. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 119 Pages.

**152A-14      Primary Eye Irritation --Technical**

**44758114** Document 14 Primary Eye Irritation Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, in Rabbits. Data Requirement: 152A-14. John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN6. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 25 Pages.

**152A-14      Primary Eye Irritation -- "WDG" End Use Product**

**44758115** Document 15 Primary Eye Irritation Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, WDG End Use in Rabbits. Data Requirement: 152A-14. John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN11. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 23 Pages.

**152A-15      Hypersensitivity Incident Reporting**

**44758116** Document 16 Hypersensitivity Incident Reporting. Data Requirement: 152A-15. Edgar R. Butts, Ph.D., Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 3, 1999. \_\_\_\_ Pages.

**152A          Hypersensitivity Testing - Technical**

**44758117** Document 17 Dermal Sensitization Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, in Guinea Pigs Using the Buehler Method. Data Requirement: 152A (870.2600). John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN7. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 27 Pages.



**152A            Potential Health Effects of *Bacillus subtilis* var. *amyloliquefaciens*  
Strain FZB24 – A Review of the Literature**

**44758118** Document 18 Potential Health Effects of *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 – A Review of the Literature. Data Requirement: 152A. Ralph I. Freudenthal, Ph.D., Consultant – Toxicology and Regulatory Affairs, 8737 Estate Drive, West Palm Beach, FL 33411. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 4, 1999. 8 Pages.

**152A            Growth Parameters of *Bacillus subtilis* var. *amyloliquefaciens*.  
Strain FZB24 at Various Temperatures**

**44758119** Document 19 Growth Parameters of *Bacillus subtilis* var. *amyloliquefaciens*. Strain FZB24, at Various Temperatures. Data Requirement: 152A. Bruce A. Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN25. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 14 Pages.

**152A            Sensitivity of Detection**

**44758120** Document 20 Sensitivity of Detection of *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24, for Toxicity/Pathogenicity Testing in Rats. Data Requirement: 152A. Bruce A. Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN1. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 33 Pages.

## ECOLOGICAL EFFECTS

### 154A-16 Avian Acute Oral Toxicity/Pathogenicity - Technical

**44758121** Document 21 *Bacillus subtilis* var. *amyloliquefaciens* - An Avian Oral Pathogenicity and Toxicity Study in the Northern Bobwhite. Data Requirement: 154A-16 (885.4050). James W. Foster, Jennie Grimes and Joann Beavers, Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Project Number: 495-101. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 21, 1998. 28 Pages.

### 154A-19 Freshwater Invertebrate Toxicity/Pathogenicity - Technical

**44758122** Document 22 *Bacillus subtilis* var. *amyloliquefaciens* - A 21-Day Life-Cycle Toxicity and Pathogenicity Test with the Cladoceran (*Daphnia magna*). Data Requirement: 154A-19 (885.4240). Kurt R. Drott and Henry O. Krueger, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Project Number: 495A-102. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 6, 1999. 36 Pages.

### 154A-20 Freshwater Fish Toxicity/Pathogenicity - Technical

**44758123** Document 23 *Bacillus subtilis* var. *amyloliquefaciens* - A Five-Concentration Toxicity and Pathogenicity Test with Rainbow Trout (*Oncorhynchus mykiss*). Data Requirement: 154A-20 (885.4200). Kurt R. Drott and Henry O. Krueger, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Project Number: 495A-101. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 6, 1999. 30 Pages.

### 154A-21 Marine/Estuarine Toxicity/Pathogenicity

Waivers are requested because of low toxicity of *Bacillus subtilis* var. *amyloliquefaciens* on aquatic species. Please see documents 22 and 23. There are no reports in the literature of *Bacillus subtilis* being insecticidal.

154A-22      Non-Target Plant Studies

Waivers are requested because of *Bacillus subtilis* var. *amyloliquefaciens* has been tested on many different crops and plants without phytotoxicity. To the contrary, *Bacillus subtilis* var. *amyloliquefaciens* will be used as a plant growth enhancer.

154A-23      Non-Target Insect Toxicity/Pathogenicity – Green Lacewing

154A-23      Non-Target Insect Toxicity/Pathogenicity – Parasitic Wasp

154A-23      Non-Target Insect Toxicity/Pathogenicity – Ladybug Beetle

Waivers are requested because of low toxicity of *Bacillus subtilis* var. *amyloliquefaciens* on insect species. Please see documents 22, 24, and 25. There are no reports in the literature of *Bacillus subtilis* being insecticidal.

154A-24      Larval Honeybee Toxicity/Pathogenicity - Technical

**44758124** Document 24 Evaluation of the Dietary Effect(s) of *Bacillus subtilis* var. *amyloliquefaciens* on Honey Bee Larvae (*Apis mellifera* L.). Data Requirement: 154A-24 (885.4380). Victor L. Maggi, M.S., California Agricultural Research, Inc., 4141 N. Vineland, Kerman, CA 93630. Study Laboratory Number: CAR 167-98. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 18, 1998. 52 Pages.

154A-24      Adult Honeybee Toxicity/Pathogenicity - Technical

**44758125** Document 25 Evaluation of the Dietary Effect(s) of *Bacillus subtilis* var. *amyloliquefaciens* on Adult Honey Bees (*Apis mellifera* L.). Data Requirement: 154A-24 (885.4380). Victor L. Maggi, M.S., California Agricultural Research, Inc., 4141 N. Vineland, Kerman, CA 93630. Study Laboratory Number: CAR 167-98. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 18, 1998. 96 Pages.

154A          Earthworm Toxicity - Technical

**44758126** Document 26 *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. Data Requirement: 154A (OECD Guideline 207). Kimberly A. Hoxter, Susan J. Palmer, and Henry O. Krueger, Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 21, 1998. 21 Pages.

154A

Algal Toxicity - Technical

**44758127** Document 27 Algae Growth Inhibition Test – Test Article: *Bacillus subtilis* Strain FZB24. Data Requirement: 154A (OECD Guideline 201). Dr. M. Jahnke, IBR Forschungs GmbH, Südkampen 31, 29664 Walsrode, GERMANY. Unpublished study conducted for FZB Biotechnik, Glienicker Weg 185, 12489 Berlin, GERMANY and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: August 29, 1994. 36 Pages.

FEB 19 1999

U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs

TAENSA, INC.  
26 SHERMAN COURT/P.O. BOX 764  
FAIRFIELD, CT 06430

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your transmittal of 02/11/99. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

26 Sherman Court • P.O. Box 764 • Fairfield, CT 06430 USA • Tel: 203-256-0460 • Fax: 203-256-0464

Via Federal Express - Standard

February 8, 1999

Dr. Phil Hutton (PM-90)(APPL)  
Biopesticides and Pollution Prevention Division  
Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

**Subject: Applications for Registration of Four Products Contain the New  
Active Ingredient – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24**  
1. TAE-022 Technical (For Manufacturing Purposes)  
2. TAE-WDG

Dear Phil:

Taensa, Inc. is applying to the Environmental Protection Agency ("EPA") for registration of the subject TAE-022 products. TAE-022 contains the microbial pest control agent, *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. TAE-022 WDG, water dispersible granule, will be the end-use product. It will be used for plant strengthening and suppression of certain diseases

On July 23, 1998, a meeting between BPPD and Taensa, Inc. was held to discuss the registration requirements for *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. It was agreed that the approval process would be more time efficient if Taensa limited the use patterns for its end-use product (TAE-022 WDG) to greenhouse/indoor and non-food uses. We will submit applications to register TAE-022 for food and terrestrial uses once this application is approved. We believe that our submission meets all points discussed and agreed to at that meeting. A copy of the letter is attached to this letter for your information.

Taensa, Inc. licensed the *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 from FZB Biotechnik GmbH in Berlin, Germany. The product has been used in various countries in Europe as a plant-strengthening agent and as a biofungicide.

## DOCUMENTS BEING SUBMITTED IN SUPPORT OF THE SUBJECT APPLICATIONS

### 1. TAE-022 Technical (For Manufacturing Purposes)

Five (5) copies of the proposed labeling, three (3) copies of supporting data and one (1) copy each of the following are attached in support of the registration of TAE-022 Technical:

- Application for Pesticide - Registration (Form 8570-1)
- Confidential Statement of Formula (Form 8570-4)
- Certification with Respect to Citation of Data (Form 8570-34)
- Data Matrix (Form 8570-35) – Agency Internal Use Copy
- Data Matrix (Form 8570-35) – Public File Copy

### 2. TAE-022 WDG

Five (5) copies of the proposed labeling and one (1) copy each of the following are attached in support of the registration of TAE-022 WDG:

- Application for Pesticide - Registration (Form 8570-1)
- Confidential Statement of Formula (Form 8570-4)
- Certification with Respect to Citation of Data (Form 8570-34)
- Data Matrix (Form 8570-35) – Agency Internal Use Copy
- Data Matrix (Form 8570-35) – Public File Copy

Data supporting the TAE-022 registration are being submitted with the TAE-022 TECHNICAL application.

Taensa appreciates the purpose of the new data matrix forms, but has prepared a "Detailed Listing of Data Submitted and Requests for Waivers to Support Application for Registration of TAE-022 Containing the New Active Ingredient *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 – February 8, 1999." The purpose of this document is to provide the reviewer with a complete compilation of studies submitted and requests for waivers for those studies not submitted to support registration of TAE-022.

## SUPPORT OF APPLICATION FOR REGISTRATION

Taensa will support its application with the data being submitted by Taensa and on its behalf, and with requests for waivers.

Should you have any questions regarding this application, please contact me. Thank you for your continued assistance.

Sincerely,



Edgar R. Butts, Ph.D.  
President and Chief Executive Officer

Enclosures



DETAILED LISTING OF DATA SUBMITTED AND REQUESTS FOR WAIVERS  
TO SUPPORT APPLICATION FOR REGISTRATION  
OF  
*BACILLUS SUBTILIS* VAR. *AMYLOLIQUEFACIENS* STRAIN FZB24  
February 8, 1999

PRODUCT CHEMISTRY

151A-10 Product Identity and Disclosure of Ingredients

- 44758101** Document 1 Product Identity and Disclosure of Ingredients – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. Data Requirement: 152A-10. Edgar R. Butts, Ph.D., Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 3, 1999. 35 Pages.

151A-11 Beginning Materials and Manufacturing Process

- 44758102** Document 2 Beginning Materials and Manufacturing Process – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. Data Requirement: 151A-11. Ulrich Korn, Ph.D. FZB Biotechnik GmbH, Glienicke Weg 185, D-12489 Berlin, GERMANY. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 5, 1999. 26 Pages.

151A-12 Discussion of Formation of Unintentional Ingredients

- 44758103** Document 3 Discussion of Formation of Unintentional Ingredients – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. Data Requirement: 151A-12. Dr. Ralph Freudenthal, Ph.D., Consultant – Toxicology and Regulatory Affairs, 8737 Estate Drive, West Palm Beach, FL 33411. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 21, 1999. 4 Pages.

151A-13 Analysis of Samples

- 44758104** Document 4 Lot Analysis of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24. Data Requirement: 151A-13 (885.1400). Bruce A. Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L03743 SN23. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 19 Pages.

**151A-15      Certification of Limits -**

**44758105** Document 5      Certification of Limits. Data Requirement: 151A-15. Edgar R. Butts, Ph.D., Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 5, 1999. 10 Pages.

**151A-16      Physical/Chemical Properties - Technical**

**44758106** Document 6      Determination of Color, Physical State, Odor, pH and Density of *Bacillus subtilis* var. *amyloliquefaciens*. Data Requirement: 151A-16 (Color 830.6302, Physical State 830.6303, Odor 830.6304, pH 830.7000, Density 830.7300). Ronda Jacobs and Willard B. Nixon, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 10, 1998. 22 Pages.

**151A-16      Physical/Chemical Properties – “WDG” End-Use Product**

**44758107** Document 7      Determination of Color, Physical State, Odor, pH and Density of *Bacillus subtilis* var. *amyloliquefaciens* “WDG” End-Use Product. Data Requirement: 151A-16 (Color 830.6302, Physical State 830.6303, Odor 830.6304, pH 830.7000, Density 830.7300). Ronda Jacobs and Willard B. Nixon, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 10, 1998. 20 Pages.

**151A-16      Physical/Chemical Properties – Corrosion Characteristics – “WDG” End-Use Product**

This study is underway and will be submitted as soon as complete.

## TOXICOLOGY

### 152A-10 Acute Oral Toxicity/Pathogenicity - Technical

**44758108** Document 8 Toxicity/Pathogenicity Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, Following Acute Oral Challenge in Rats. Data Requirement: 152A-10 (885.3050). Kelly A. Harrington, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN2. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 123 Pages.

### 152A-10 Acute Oral Toxicity – “WDG” End-Use Product

**44758109** Document 9 Acute Toxicity/Limit Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, WDG End Use Product, Following Acute Oral Challenge in Rats. Data Requirement: 152A-10 (870.1100). Bruce Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN8. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 29 Pages.

### 152A-11 Acute Dermal Toxicity/Pathogenicity - Technical

**44758110** Document 10 Acute Dermal Toxicity/Pathology Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, in Rabbits. Data Requirement: 152A-11 (885.3100). John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN5. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 28 Pages.

**152A-11      Acute Dermal Toxicity/Pathogenicity – “WDG” End-Use Product**

**44758111**    Document 11    Acute Dermal Toxicity/Pathology Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, WDG End Use Product in Rabbits. Data Requirement: 152A-11 (885.3100). John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN10. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 28 Pages.

**152A-12      Acute Pulmonary Toxicity/Pathogenicity - Technical**

**44758112**    Document 12    Toxicity/Pathogenicity Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, Following Acute Intratracheal Challenge in Rats. Data Requirement: 152A-12 (885.3150). Kelly A. Harrington, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN3. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 133 Pages.

**152A-12      Acute Inhalation Toxicity -“WDG” End-Use Product**

This study is underway and will be submitted as soon as complete.

**152A-13      Acute Intravenous Toxicity/Pathogenicity - Technical**

**44758113**    Document 13    Toxicity/Pathogenicity Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, Following Acute Intravenous Challenge in Rats. Data Requirement: 152A-13 (885.3200). Bruce A. Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN4. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 119 Pages.

**152A-14      Primary Eye Irritation --Technical**

**44758114** Document 14 Primary Eye Irritation Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, in Rabbits. Data Requirement: 152A-14. John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN6. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 25 Pages.

**152A-14      Primary Eye Irritation – “WDG”End Use Product**

**44758115** Document 15 Primary Eye Irritation Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, WDG End Use in Rabbits. Data Requirement: 152A-14. John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN11. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 23 Pages.

**152A-15      Hypersensitivity Incident Reporting**

**44758116** Document 16 Hypersensitivity Incident Reporting. Data Requirement: 152A-15. Edgar R. Butts, Ph.D., Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 3, 1999. \_\_\_\_ Pages.

**152A      Hypersensitivity Testing - Technical**

**44758117** Document 17 Dermal Sensitization Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, in Guinea Pigs Using the Buehler Method. Data Requirement: 152A (870.2600). John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN7. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 27 Pages.

152A      Potential Health Effects of *Bacillus subtilis* var. *amyloliquefaciens*  
Strain FZB24 – A Review of the Literature

44758118 Document 18 Potential Health Effects of *Bacillus subtilis* var.  
*amyloliquefaciens* Strain FZB24 – A Review of the  
Literature. Data Requirement: 152A. Ralph I.  
Freudenthal, Ph.D., Consultant – Toxicology and  
Regulatory Affairs, 8737 Estate Drive, West Palm Beach,  
FL 33411. Unpublished study conducted for and  
submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT  
06430. Completion Date: February 4, 1999. 8 Pages.

152A      Growth Parameters of *Bacillus subtilis* var. *amyloliquefaciens*.  
Strain FZB24 at Various Temperatures

44758119 Document 19 Growth Parameters of *Bacillus subtilis* var.  
*amyloliquefaciens*. Strain FZB24, at Various  
Temperatures. Data Requirement: 152A. Bruce A.  
Gingras, Ph.D., IIT Research Institute, Life Sciences  
Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-  
3799. Laboratory Project Identity: L08743 SN25.  
Unpublished study conducted for and submitted by  
Taensa, Inc., P.O. Box 764, Fairfield, CT 06430.  
Completion Date: January 1999. 14 Pages.

152A      Sensitivity of Detection

44758120 Document 20 Sensitivity of Detection of *Bacillus subtilis* var.  
*amyloliquefaciens* Strain FZB24, for Toxicity/Pathogenicity  
Testing in Rats. Data Requirement: 152A. Bruce A.  
Gingras, Ph.D., IIT Research Institute, Life Sciences  
Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-  
3799. Laboratory Project Identity: L08743 SN1.  
Unpublished study conducted for and submitted by  
Taensa, Inc., P.O. Box 764, Fairfield, CT 06430.  
Completion Date: December 1998. 33 Pages.

## ECOLOGICAL EFFECTS

### 154A-16 Avian Acute Oral Toxicity/Pathogenicity - Technical

**44758121** Document 21 *Bacillus subtilis* var. *amyloliquefaciens* - An Avian Oral Pathogenicity and Toxicity Study in the Northern Bobwhite. Data Requirement: 154A-16 (885.4050). James W. Foster, Jennie Grimes and Joann Beavers, Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Project Number: 495-101. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 21, 1998. 28 Pages.

### 154A-19 Freshwater Invertebrate Toxicity/Pathogenicity - Technical

**44758122** Document 22 *Bacillus subtilis* var. *amyloliquefaciens* - A 21-Day Life-Cycle Toxicity and Pathogenicity Test with the Cladoceran (*Daphnia magna*). Data Requirement: 154A-19 (885.4240). Kurt R. Drott and Henry O. Krueger, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Project Number: 495A-102. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 6, 1999. 36 Pages.

### 154A-20 Freshwater Fish Toxicity/Pathogenicity - Technical

**44758123** Document 23 *Bacillus subtilis* var. *amyloliquefaciens* - A Five-Concentration Toxicity and Pathogenicity Test with Rainbow Trout (*Oncorhynchus mykiss*). Data Requirement: 154A-20 (885.4200). Kurt R. Drott and Henry O. Krueger, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Project Number: 495A-101. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 6, 1999. 30 Pages.

### 154A-21 Marine/Estuarine Toxicity/Pathogenicity

Waivers are requested because of low toxicity of *Bacillus subtilis* var. *amyloliquefaciens* on aquatic species. Please see documents 22 and 23. There are no reports in the literature of *Bacillus subtilis* being insecticidal.



**154A-22 Non-Target Plant Studies**

Waivers are requested because of *Bacillus subtilis* var. *amyloliquefaciens* has been tested on many different crops and plants without phytotoxicity. To the contrary, *Bacillus subtilis* var. *amyloliquefaciens* will be used as a plant growth enhancer.

**154A-23 Non-Target Insect Toxicity/Pathogenicity – Green Lacewing**  
**154A-23 Non-Target Insect Toxicity/Pathogenicity – Parasitic Wasp**  
**154A-23 Non-Target Insect Toxicity/Pathogenicity – Ladybug Beetle**

Waivers are requested because of low toxicity of *Bacillus subtilis* var. *amyloliquefaciens* on insect species. Please see documents 22, 24, and 25. There are no reports in the literature of *Bacillus subtilis* being insecticidal.

**154A-24 Larval Honeybee Toxicity/Pathogenicity - Technical**

**44758124** Document 24 Evaluation of the Dietary Effect(s) of *Bacillus subtilis* var. *amyloliquefaciens* on Honey Bee Larvae (*Apis mellifera* L.). Data Requirement: 154A-24 (885.4380). Victor L. Maggi, M.S., California Agricultural Research, Inc., 4141 N. Vineland, Kerman, CA 93630. Study Laboratory Number: CAR 167-98. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 18, 1998. 52 Pages.

**154A-24 Adult Honeybee Toxicity/Pathogenicity - Technical**

**44758125** Document 25 Evaluation of the Dietary Effect(s) of *Bacillus subtilis* var. *amyloliquefaciens* on Adult Honey Bees (*Apis mellifera* L.). Data Requirement: 154A-24 (885.4380). Victor L. Maggi, M.S., California Agricultural Research, Inc., 4141 N. Vineland, Kerman, CA 93630. Study Laboratory Number: CAR 167-98. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 18, 1998. 96 Pages.

**154A Earthworm Toxicity - Technical**

**44758126** Document 26 *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. Data Requirement: 154A (OECD Guideline 207). Kimberly A. Hoxter, Susan J. Palmei, and Henry O. Krueger, Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 21, 1998. 21 Pages.

154A

Algal Toxicity - Technical

44758127 Document 27 Algae Growth Inhibition Test – Test Article: *Bacillus subtilis* Strain FZB24. Data Requirement: 154A (OECD Guideline 201). Dr. M. Jahnke, IBR Forschungs GmbH, Südkampen 31, 29664 Walsrode, GERMANY. Unpublished study conducted for FZB Biotechnik, Glienicker Weg 185, 12489 Berlin, GERMANY and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: August 29, 1994. 36 Pages.

R. Rose 7511C

This document will publish in the  
FEDERAL REGISTER of 6/16/99.  
Approximately 24 hours after  
publication, page numbers are  
available by calling the Federal  
Register Staff (FRS) at 202-260-2253.  
Please refer to the FRL number at  
the top of the first page or the  
number at the bottom left corner of  
the first page.

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(2 Mail G-304).

John A. Richards, Director  
Federal Register Staff

## ENVIRONMENTAL PROTECTION AGENCY

[OPP-30480; FRL-6084-5]

### Certain Companies; Applications to Register Pesticide Products

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** This notice announces receipt of applications to register pesticide products containing new active ingredients not included in any previously registered products pursuant to the provisions of section 3(c)(4) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended.

**DATES:** Written comments must be submitted by (*insert date 30 days after date of publication in the Federal Register*).

**ADDRESSES:** By mail, submit written comments identified by the document control number [OPP-30480] and the file symbols to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring comments to: Environmental Protection Agency, Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Comments and data may also be submitted electronically to: opp-docket@epamail.epa.gov. Follow the instructions under "SUPPLEMENTARY INFORMATION." No Confidential Business Information (CBI) should be submitted through e-mail.

Information submitted as a comment concerning this notice may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice. The public docket is available for public inspection in Rm. 119 at the Virginia address given above, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding holidays.

**FOR FURTHER INFORMATION CONTACT:** The Regulatory Action Leader, Biopesticides and Pollution Prevention Division (7511C), listed in the table below:

Regulatory Action Leader	Office location/telephone number	Address
Robyn Rose .....	Rm. 910W44, CM #2, 703-308-9581, e-mail: rose.robyn@epa.gov	1921 Jefferson Davis Hwy, Arlington, VA
Susanne Cerrelli .....	Rm. 910W45, CM #2, 703-308-8077, e-mail: cerrelli.susanne@epa.gov	Do.

**SUPPLEMENTARY INFORMATION:** EPA received applications as follows to register pesticide products containing active ingredients not included in any previously registered products pursuant to the provision of section 3(c)(4) of FIFRA. Notice

of receipt of these applications does not imply a decision by the Agency on the applications.

### **I. Products Containing Active Ingredients Not Included In Any Previously Registered Products**

1. File Symbol: 72098-A. Applicant: Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430. Product Name: TAE-022 Technical. Plant Strengthening Agent and Biofungicide. Active ingredient: *Bacillus subtilis* var. *amyloliquefaciens* strain FZB24 at 73.3%. Proposed classification/Use: None. For manufacturing purposes only. (R. Rose)

2. File Symbol: 69592-L. Applicant: Agraquest Inc., 1105 Kennedy Place, Davis, CA 95616. Product Name: QST 713 Technical. Microbial Fungicide. Active ingredient: QST 713 strain of dried *Bacillus subtilis* at 5%. Proposed classification/Use: None. For use in manufacturing or formulating end-use products to control various fungal plant pathogens and terrestrial use. (S. Cerrelli)

Notice of approval or denial of an application to register a pesticide product will be announced in the **Federal Register**. The procedure for requesting data will be given in the **Federal Register** if an application is approved.

Comments received within the specified time period will be considered before a final decision is made; comments received after the time specified will be considered only to the extent possible without delaying processing of the application.

### **II. Public Record and Electronic Submissions**

The official record for this notice, as well as the public version, has been established for this notice under docket number [OPP-30480] (including comments and data submitted electronically as described below). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The official notice record is located at the address in "ADDRESSES" at the beginning of this document.

Electronic comments can be sent directly to EPA at:

opp-docket@epamail.epa.gov

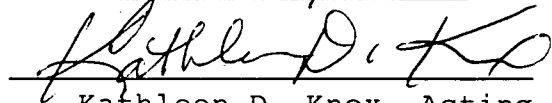
Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Comment and data will also be accepted on disks in Wordperfect 5.1/6.1 or ASCII file format. All comments and data in electronic form must be identified by the docket number [OPP-30480]. Electronic comments on this notice may be filed online at many Federal Depository Libraries.

**Authority:** 7 U.S.C. 136.

**List of Subjects**

Environmental protection, Pesticides and pest, Product registration.

Dated: June 7, 1999



Kathleen D. Knox, Acting  
Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 99-????? Filed ??-??-99; 8:45 am]

**BILLING CODE 6560-50-F**

Certified to be a true  
copy of the original.





FRONT END PROCESSING FORM TO FILE ROOM

DATE 2/16/99

FILE NUMBER 72098-A

☐ No Data - File Room "Make Ready for                     "  
(FM or Individual)

☒ Data - File Room "Assign Jacket to Shelf"

☐ Rejected - File Room "Assign Jacket to Rejected Shelf"

FRONT END PROCESSING APPLICATION INFORMATION CHECK

PM 92

EPA COMPANY NUMBER 72098-A

EPA REGISTRATION NUMBER  
STATUS (For Amendments)

Active \_\_\_\_\_ Cancelled \_\_\_\_\_

Not in REFS \_\_\_\_\_

"ME-TOO" CITED PRODUCT STATUS

Active \_\_\_\_\_ Cancelled \_\_\_\_\_

Not in REFS \_\_\_\_\_

PRAT RECORD CREATED yes-2/12/98



NIET

Please read instructions on reverse before completing form.

Form Approved. OMB No. 2070-0060, Approval expires 2-28-95



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

260536  
259579

## Application for Pesticide - Section I

1. Company/Product Number

72098- A

2. EPA Product Manager

Dr. Phil Hutton - 90

3. Proposed Classification

☒ None ☐ Restricted

4. Company/Product (Name)

TAE-022 Technical

PM#

992 92

5. Name and Address of Applicant (Include ZIP Code)

Taensa, Inc.

26 Sherman Court, P.O. Box 764, Fairfield, CT 06430

6. **Expedited Review.** In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to:

EPA Reg. No. \_\_\_\_\_

Product Name \_\_\_\_\_

☐ Check if this is a new address

## Section - II

☐ Amendment - Explain below.

☐ Resubmission in response to Agency letter dated \_\_\_\_\_

☐ Notification - Explain below.

☐ Final printed labels in response to Agency letter dated \_\_\_\_\_

☐ "Me Too" Application.

☒ Other - Explain below.

**Explanation:** Use additional page(s) if necessary. (For section I and Section II.)

New application to register an active ingredient not previously registered with EPA.

## Section - III

1. Material This Product Will Be Packaged In:

Child-Resistant Packaging

☐ Yes  
☒ No

Unit Packaging

☐ Yes  
☒ No

Water Soluble Packaging

☐ Yes  
☒ No

2. Type of Container

☒ Metal  
☒ Plastic  
☐ Glass  
☐ Paper  
☐ Other (Specify) \_\_\_\_\_

\* Certification must submitted

If "Yes"  
Unit Packaging wgt.

No. per  
container

If "Yes"  
Package wgt

No. per  
container

3. Location of Net Contents Information

☒ Label ☐ Container

4. Size(s) Retail Container

5, 10, 20, 40 Kg, Bulk

5. Location of Label Directions

☒ On Container

6. Manner in Which Label is Affixed to Product

☒ Lithograph  
☒ Paper glued  
☐ Stenciled

☐ Other \_\_\_\_\_

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)

Name

Edgar R. Butts, Ph.D.

Title

President and CEO

Telephone No. (Include Area Code)

203-256-0460

## Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

6. Date Application Received

(Stamped)

2. Signature

Edgar R Butts

3. Title

President and CEO

4. Typed Name

Edgar R. Butts, Ph.D.

5. Date

2/8/99





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

260536

## Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code)  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input checked="" type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

-VOID-

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
<b>Certification must be submitted</b>	If "Yes" Unit Packaging wgt.	No. per container			
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name		Title		Telephone No. (Include Area Code)	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received  <b>(Stamped)</b>
2. Signature		3. Title			
4. Typed Name		5. Date			



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, end use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). [If not exempted by 40 CFR 152.81 (b) (4)];
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

**SECTION III** (Packaging and Container Information) - This Section must be completed for all applications submitted in connection with new registration or applicable amendments.

1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
2. **Type of Retail Container** - Indicate type of container in which product will be marketed.
3. **Location of Net Contents** - Indicate the location of the net contents information for your product.
4. **Size(s) of Retail Container** - Specify the net contents of all retail containers for your product.
5. **Location of Use Directions** - Indicate the location of the use directions for your product.
6. **Manner in which label is affixed to product** - Indicate the method product label is attached to retail container.

**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.





United States  
Environmental Protection Agency  
Washington, DC 20460

☐ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

260536  
~~260536~~

## Application for Pesticide - Section I

1. Company/Product Number	2. EPA Product Manager	3. Proposed Classification <input type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name)	PM#	
5. Name and Address of Applicant (Include ZIP Code)  <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input checked="" type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

VOID

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes* <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input type="checkbox"/> Other (Specify) _____	
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____	

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name		Title		Telephone No. (Include Area Code)	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature		3. Title			
4. Typed Name		5. Date			



## PAPERWORK REDUCTION ACT NOTICE and INSTRUCTIONS

**PAPERWORK REDUCTION ACT NOTICE:** Public reporting burden for this collection of information is estimated to average 0.85 hour per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, (2136), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, DC 20460.

**INSTRUCTIONS:** This form is to be used for all applications for new registration, and use reregistration, amendment, resubmission, to applications for notifications, final printed labeling, reregistration, etc. In order to process an application for a new registration submitted on this form, the following material must accompany the application:

1. Certification with Respect to Citation of Data (EPA Form 8570-29). (If not exempted by 40 CFR 152.81 (b) (4));
2. Confidential Statement of Formula (EPA Form 8570-4);
3. Formulator's Exemption Statement (EPA Form 8570-27);
4. Five copies of draft labeling;
5. Three copies of any data submitted;
6. Authorization letter where applicable;
7. Matrices where applicable.

**Submission of Labeling** - Labeling should first be submitted in the form of draft labels with all applications for new registration. Such draft labels may be in the form of typed label text on 8.5 x 11 inch paper for submission or a mockup of the proposed label. If prepared for mockup, it should be constructed in a way as to facilitate storage in an 8.5 x 11 inch file. Mockup labels significantly smaller than 8.5 x 11 inches should be mounted on 8.5 x 11 inch paper for submission.

**Submission of Data** - Data submitted in support of this application must be submitted in accordance with PR Notice 86-5.

**SPECIFIC INSTRUCTIONS:** Please read the instructions listed below before completing this application. First determine the type of registration action, listed in Block A, for which you are submitting this application. For applications submitted in connection with New Registration actions, Sections I, III, and IV must be completed by the applicant. For applications submitted in connection with amended reregistration actions, resubmissions, notifications, reregistrations, etc., Sections I, II, and IV must be completed by the applicant.

**Block A** - Check the appropriate action for which you are submitting this form.

**SECTION I** - This section must be completed, as applicable, for all registration actions.

1. **Company/Product Number** - Insert your Company Number, if one has been assigned by EPA. This number may have been assigned to you as a basic registrant, a distributor, or as an establishment. If your product is registered, insert the Product Number.
2. **EPA Product Manager** - If known, fill in the name and PM number of the EPA Product Manager.
3. **Proposed Classification** - Specify the proposed classification of this product.
4. **Product Name** - Enter the complete product name of this pesticide as it will appear on the label. The name must be specific to this product only. Duplication of names is not permitted among products of the same company. Do not include any brand name or company line designations.
5. **Name and Address of Applicant** - The name of the firm or person and address shown in your application is the person or firm to whom the registration will be issued. If you are acting in behalf of another party, you must submit authorization from that party to act for them in registration matters. An applicant not residing in the United States must have an authorized agent residing in the United States to act for them in all registration matters. The name and complete mailing address of such an agent must accompany this application.
6. **Expedited Review** - FIFRA section 3 (c) 3 (B) provides for expedited review of applications for registration, or amendments to existing registrations, that are similar or identical to other pesticide products that are currently registered with the EPA. In order for your application to be eligible for expedited review, you must provide us with the EPA Registration Number and product name of the product you believe is similar to or identical to your product. The product must be similar or identical in both formulation and labeled uses.

**SECTION II** - This section must be completed for all applications submitted to amend the registration only of a currently registered product (Amendment), for a resubmission in response to an Agency letter, for notifications to the Agency, for the submission of final printed labeling, for reregistration and for any other action that pertains to a specific EPA-registered product. This section is not to be used for a new application for registration.

1. **Subject of submission** - Check the applicable block and provide the Agency letter date if appropriate. Provide a brief explanation of the purpose(s) for the submission, such as "the addition of a site, pest or crop (specify)"; "amend the Confidential Statement of Formula by..."; "reregistration submission"; "general label revision of use directions." Attach a separate page if additional space is needed.

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1. **Type of Packaging** - Check the appropriate block if your product will be packaged in the indicated packaging types. Indicate the size of the individual packets and number per retail container.
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**SECTION IV** (Contact Point) - This Section must be completed for all applications for Registration actions, i.e., new products registration, resubmission, "me-too," reregistration, etc.

- 1-5. Self-explanatory.
6. EPA Use Only.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

January 12, 1999

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Taensa, Inc.  
26 Sherman Court  
P.O. Box 764  
Fairfield, CT 06430

PRODUCT NAME: TAE-022 Technical  
COMPANY NAME: Taensa, Inc.  
OPP IDENTIFICATION NUMBER: 260536  
EPA FILE SYMBOL: 72098-A  
EPA RECEIPT DATE: 02/11/99

SUBJECT: RECEIPT OF APPLICATION FOR A NEW REGISTRATION

DEAR REGISTRANT:

The Office of Pesticides Programs has received your application for a new registration and it has passed an administrative screen for completeness

Please note that this is only a notification of receipt of your application. This is only the first step in the application process, and does NOT constitute approval..

If you have any questions please contact Phil Hutton, Product Manager 92, at (703)-308-8260.

Sincerely,

A handwritten signature in cursive script, appearing to read "Annie L. Jones".

Front End Processing Staff  
Information Services Branch  
Information Resources & Services Division



## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.  
WASHINGTON, D.C. 20460

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the completed form to this address.

## Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address, and Telephone Number  
Taensa, Inc., 26 Sherman Court, P. O. Box 764, Fairfield, CT 06430 USA, Tel. 203-256-0460

EPA Registration Number/File Symbol – 72098-A

Active Ingredient(s) and/or representative test compound(s) – *Bacillus subtilis* var.  
*amyloliquefaciens* Strain; CAS Number – Microbial/Not applicable

Date – February 8, 1999

General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158)  
Greenhouse Non-Food; Indoor

Product Name – TAE-022 Technical

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).



I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

## SECTION I: METHOD OF DATA SUPPORT (Check one method only)



I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).



I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

## SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]



I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

## SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature

*Edgar R Butts*

Date

2/8/99

Typed or Printed Name and Title

Edgar R. Butts, Ph.D., President and CEO



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

**Paperwork Reduction Act Notice:** The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date February 8, 1999	EPA Reg No./File Symbol – 72098- <i>A</i>	Page 1 of 2
Applicant's/Registrant's Name & Address Taensa, Inc., 26 Sherman Court, P. O. Box 764, Fairfield, CT 06430 USA, Tel. 203-256-0460		Product – TAE-022 TECHNICAL

Ingredient – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24; CAS Number – Microbial/Not applicable

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
151A-10	Product Identity and Disclosure of Ingredients		Taensa, Inc.	OWN	Document 1
151A-11	Beginning Materials and Manufacturing Process		Taensa, Inc.	OWN	Document 2
151A-12	Discussion of Formation of Unintentional Ingredients		Taensa, Inc.	OWN	Document 3
151A-13	Analysis of Samples		Taensa, Inc.	OWN	Document 4
151A-15	Certification of Limits		Taensa, Inc.	OWN	Document 5
151A-16	Physical and Chemical Properties – Technical		Taensa, Inc.	OWN	Document 6
151A-16	Physical and Chemical Properties – End-Use Product		Taensa, Inc.	OWN	Document 7
152A-10	Acute Oral Toxicity/Pathogenicity – Technical		Taensa, Inc.	OWN	Document 8
152A-10	Acute Oral Toxicity – End-Use Product		Taensa, Inc.	OWN	Document 9
152A-11	Acute Dermal Toxicity/Pathogenicity – Technical		Taensa, Inc.	OWN	Document 10
152A-11	Acute Dermal Toxicity/Pathogenicity – End-Use Product		Taensa, Inc.	OWN	Document 11
152A-12	Acute Pulmonary Toxicity/Pathogenicity – Technical		Taensa, Inc.	OWN	Document 12
152A-13	Acute Intravenous Toxicity/Pathogenicity – Technical		Taensa, Inc.	OWN	Document 13
152A-14	Primary Eye Irritation - Technical		Taensa, Inc.	OWN	Document 14
152A-14	Primary Eye Irritation – End-Use Product		Taensa, Inc.	OWN	Document 15

Signature <i>Edgar R Butts</i>	Name and Title Edgar R. Butts, Ph.D., President and CEO	Date <i>2/8/99</i>
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
401 M Street, S.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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**DATA MATRIX**

Date February 8, 1999			EPA Reg No./File Symbol – 72098- <i>A</i>		Page 2 of 2
Applicant's/Registrant's Name & Address Taensa, Inc., 26 Sherman Court, P. O. Box 764, Fairfield, CT 06430 USA, Tel. 203-256-0460			Product – TAE-022 TECHNICAL		
Ingredient – <i>Bacillus subtilis</i> var. <i>amyloliquefaciens</i> Strain FZB24; CAS Number – Microbial/Not applicable					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
152A-15	Hypersensitivity Incident Reporting		Taensa, Inc.	OWN	Document 16
152A	Hypersensitivity Testing		Taensa, Inc.	OWN	Document 17
152A	Potential Health Effects – Literature Review – Special Study		Taensa, Inc.	OWN	Document 18
152A	Growth Parameters at Various Temperatures – Special Study		Taensa, Inc.	OWN	Document 19
152A	Sensitivity of Detection		Taensa, Inc.	OWN	Document 20
154A-16	Avian Acute Oral Toxicity/Pathogenicity		Taensa, Inc.	OWN	Document 21
154A-19	Freshwater Invertebrate Toxicity/Pathogenicity		Taensa, Inc.	OWN	Document 22
154A-20	Freshwater Fish Toxicity/Pathogenicity		Taensa, Inc.	OWN	Document 23
154A-24	Larval Honeybee Toxicity/Pathogenicity		Taensa, Inc.	OWN	Document 24
154A-24	Adult Honeybee Toxicity/Pathogenicity		Taensa, Inc.	OWN	Document 25
154A-	Earthworm Toxicity		Taensa, Inc.	OWN	Document 26
154A-	Algal Toxicity		Taensa, Inc.	OWN	Document 27
Signature <i>Edgar R Butts</i>			Name and Title Edgar R. Butts, Ph.D., President and CEO		Date 2/8/99

# TAE-022 TECHNICAL

## FOR MANUFACTURING PURPOSES ONLY

	% w/w
<b>ACTIVE INGREDIENT</b> – <i>Bacillus subtilis</i> var. <i>amyloliquefaciens</i> Strain FZB24*.....	73.3%
<b>OTHER INGREDIENTS</b> .....	26.7%
Total	100.0%

\* Contains  $5.0 \times 10^{11}$  Colony Forming Units ("CFU")/gram.

### KEEP OUT OF REACH OF CHILDREN

## WARNING

### PRECAUTIONARY STATEMENTS

### HAZARDS TO HUMANS AND DOMESTIC ANIMALS

## WARNING

Causes substantial but temporary eye injury. Do not get in eyes. Wear protective eyewear (goggles, face shield, or safety glasses). Harmful if swallowed, absorbed through skin, or inhaled. Avoid contact with skin, eyes, or clothing. Avoid breathing dust. Remove contaminated clothing and wash clothing before reuse. Wash thoroughly with soap and water after handling.

### FIRST AID

**IF IN EYES:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. Get medical attention.

**IF SWALLOWED:** Call a physician or Poison Control Center. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger, or if available, by administering syrup of ipecac. If a person is unconscious, do not give anything by mouth and do not induce vomiting.

**IF ON SKIN OR CLOTHING:** Wash with plenty of soap and water. Get medical attention if irritation persists.

**IF INHALED** - Remove victim to fresh air. If not breathing, give artificial respiration, preferably mouth to mouth. Get medical attention.

### EMERGENCY INFORMATION

For spill, leak, fire, exposure, or accident call CHEMTREC at 1-800-424-9300.

### ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

Net Contents \_\_\_\_\_

Taensa, Inc.  
26 Sherman Court  
P.O. Box 764  
Fairfield, CT 06430 U.S.A.

EPA Establishment Number 72098-A  
EPA Registration Number 72098-A  
Made in U.S.A.  
Revision: 990208

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Only for formulation into product for the following use:

- For plant strengthening, growth enhancement and suppression of certain diseases

This product may be used to formulate products for any additional use(s) not listed on the TAE-022 Technical label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding the support of such use(s).

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

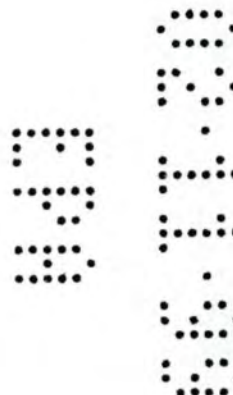
**STORAGE:** TAE-022 consists of living microbes. Store in a cool dry place. Do not freeze or expose to temperatures above 80° F. Opened packages should be closed tightly and stored in a cool dry place and used within one month.

**PESTICIDE DISPOSAL:** Unused TAE-022 Technical and wastes resulting from the use of this product may be disposed of in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

**CONTAINER DISPOSAL:** Dispose of empty bag in a sanitary landfill or by incineration, or if allowed by State and local authorities, by burning. If burned, stay out of smoke.

## CONDITIONS OF SALE

Taensa, Inc. warrants that the product conforms to its chemical description and is reasonably fit for the purpose stated on the label when used in accordance with directions under normal conditions of use, but neither this warranty nor any other warranty of merchantability or fitness for a particular purpose, express or implied, extends to the use of this product contrary to label instructions, or under abnormal conditions or under conditions not reasonably foreseeable to manufacturer, and buyer assumes the risk for any such use.





# Taensa, Inc.

26 Sherman Court  
P.O. Box 764  
Fairfield, CT 06430

Telephone: 203-256-0460  
Fax: 203-256-0464  
e-mail: <erb@taensa.com>

Via Federal Express - Standard

July 29, 1998

Dr. Phil Hutton (PM-90)  
Biopesticides and Pollution Prevention Division  
Office of Pesticide Programs  
Environmental Protection Agency  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Highway  
Arlington, VA 22202

COPY

**Subject: Minutes of Meeting Between the Biopesticides and Pollution Prevention Division (BPPD) and Taensa, Inc. Regarding the Data Requirements to Support the Registration of the Microbial Pest Control Agent, *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24**

Dear Phil:

Thank you very much for meeting with us on July 23, 1998, to discuss the data requirements to support the registration of *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 with EPA. I would like to confirm our understanding of these requirements, since we intend to initiate our data development program immediately.

Persons attending the meeting on behalf of BPPD were Ms. Linda Hollis, Dr. Phil Hutton, Dr. John Kough, Mr. Willie Nelson, Mr. Bob Torla, Dr. Freshtah Toghrol, Dr. Zig Viatuzis, and Dr. Chris Wozniak. Dr. Ralph Freudenthal and Dr. Edgar Butts attended the meeting on behalf of Taensa, Inc.

## Background and Anticipated Uses

Taensa, Inc. has licensed the use of *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 from FZB Biotechnik GmbH (FZB), Berlin, Germany, and plans to commercialize it by year 2000 in the United States and in other countries. Taensa will initially focus on plant strengthening effects and control/suppression of soil-born plant pathogens in high value crops, such as ornamentals, vegetables, trees and vines, and turf. *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 ("FZB24") has been tested exhaustively and has been demonstrated efficacious. It appears to be an excellent candidate for integrated pest management.

## Description of Product

FZB24 was isolated in Germany and has not been genetically modified. Taensa will refer to the FZB24 using its internal product code of TAE-022.

FZB24 was originally isolated in Germany. It has been identified by Deutsche Sammlung von Mikroorganismen (DSM) as *Bacillus amyloliquefaciens*. I have been told by FZB that *Bacillus amyloliquefaciens* is a subgroup of *Bacillus subtilis*. FZB has significant experience in the



identification of *Bacillus* group, including *Bacillus subtilis*. FZB24 was clearly identified by FZB as *Bacillus subtilis*. Further, FZB using various assay methods including selected fatty acid analyses, identified FZB24 as *Bacillus subtilis*. In discussions with FZB, it was agreed that Taensa would propose referring to FZB24 as *Bacillus subtilis* subspecies *amyloliquefaciens*. This nomenclature is consistent with identifications of DSM and FZB.

#### PPQ/APHIS/USDA Form 526 – Courtesy Permit

Taensa has obtained a courtesy permit (PPQ/APHIS/USDA Form 526) from PPQ/APHIS/USDA indicating that *Bacillus subtilis* var. *amyloliquefaciens* (FZB24) is not subject to the rules and regulations of the Federal Plant Pest Act.

#### Data Requirements

It is our understanding that the following data are required to register *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 (TAE-001) under the Subdivision M Guidelines:

#### Product Chemistry

151A-10 885.1100	Product Identity <ul style="list-style-type: none"> <li>Identified by DSM</li> <li>Will submit light and EM photographs</li> </ul>
151A-11 885.1200	Manufacturing Process
151A-12 885.1300	Discussion Impurity Formation
151A-13 885.1400	Analysis of Samples <ul style="list-style-type: none"> <li>Colony Forming Units/Gram</li> <li>Per Cent By Weight</li> <li>Will provide quality assurance and quality control standard operating procedures to screen for pathogenic bacteria for technical and formulated product.</li> </ul>
151A-15 885.1500	Certification of Limits
151A-16	Physical/Chemical Properties <ul style="list-style-type: none"> <li>Color (Technical, End Use Product)</li> <li>Physical State (Technical, End Use Product)</li> <li>Odor (Technical, End Use Product)</li> <li>Density or Specific Gravity (Technical, End Use Product)</li> <li>pH (Technical, End Use Product)</li> <li>Corrosion Characteristics (End Use Product)</li> <li>Stability (Technical, California and International Only)</li> <li>Storage Stability (End Use Product, California and International Only)</li> </ul>

## Toxicology

152A-10 885.3050	Acute Oral Toxicity/Pathogenicity (Technical) • Full Study - All Clinical and Clearance End-Points
152A-10	Acute Oral Toxicity (End Use Product, California Only)
152A-11 885.3100	Acute Dermal Toxicity/Irritation (Technical, End Use Product)
152A-12 885.3150	Acute Pulmonary Toxicity/Pathogenicity (Technical) • Full Study - All Clinical and Clearance End-Points
152A-13 885.3200	Acute Intravenous Toxicity/Pathogenicity (Technical) • Full Study - All Clinical and Clearance End-Points
152A-14	Primary Eye Irritation (Technical, End Use Product)
152A-15 885.3400	Hypersensitivity Incident Reporting

Taensa will also conduct a temperature study to determine the maximum and minimum temperatures at which Strain FZB24 will grow.

## Ecological Effects

It was agreed, pending the appropriate literature searches, that no ecological data are required to support the greenhouse use of *Bacillus subtilis* subspecies *amyloliquefaciens*.

154A-16 885.4050	Avian Acute Oral Toxicity/Pathogenicity • Waiver to be requested - Greenhouse use - Low potential for exposure. Will conduct and submit for outdoor uses.
154A-19 885.4240	Freshwater Invertebrate Toxicity/Pathogenicity • Waiver to be requested - Greenhouse use - Low potential for exposure. Will conduct and submit for outdoor uses.
154A-20 885.4200	Freshwater Fish Toxicity/Pathogenicity • Waiver to be requested - Greenhouse use - Low potential for exposure. Will conduct and submit for outdoor uses.
154A-21 885.4280	Marine/Estuarine Toxicity/Pathogenicity • Waiver to be requested - Greenhouse use - Low potential for exposure. • Waiver for outdoor to be requested because of low potential for toxicity - to be supported by literature search and review.
154A-22 885.4300	Nontarget Plant Studies • Waiver to be requested - Greenhouse use - Low potential for exposure. • Waiver for outdoor to be requested because of low potential for toxicity - to be supported by submitted review of data from field trials and literature search and review.
154A-23 885.4340	Nontarget Insect Toxicity/Pathogenicity • Waiver to be requested - Greenhouse use - Low potential for exposure. • Waiver for outdoor uses to be requested because of low potential for toxicity - to be supported by submitted literature search and review.
154A-24 885.4380	Honeybee Toxicity/Pathogenicity • Waiver to be requested - Greenhouse use - Low potential for exposure. • Will conduct for both mature and immature honeybees.

## Anticipated Submission Timing and Sequence

Taensa will submit the following three applications for *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24:

1. Greenhouse Non-Food Uses – It is our understanding that approval for this use pattern will be faster than approval for an outdoor use. It will require less review time because ecological effects data will not be required and because less Federal Register publications are required.
2. Greenhouse and Outdoor Food and Non-Food Uses – This label will provide Taensa with its full-use label. Whether or not this is an amendment to the aforementioned "Greenhouse Non-Food Uses" application or a separate application will be determined based on discussions with BPPD.
3. Technical or Manufacturing Use Product – Will be requested to facilitate formulation by a third party, if necessary. It is anticipated that the manufacturer of the product will also formulate it.

### Registration of Additional Strains *Bacillus subtilis* by Bridging Data

We discussed the possibility of registering additional strains of *Bacillus subtilis* by bridging certain data. It is understood that the following additional data would be required to register additional strains or varieties of *Bacillus subtilis* depending on use pattern:

- Product Chemistry – Complete package
- Toxicology – Acute oral toxicity study (technical)
- Ecological Effects – Depends on use pattern – should discuss with RAL

### Additional Studies That May Be Conducted

Further, Taensa also plans to register *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 internationally. We anticipate developing the following data to support these registration efforts:

- Hypersensitivity Testing (Technical, End-Use; International Only)
- Acute Oral Toxicity (End-Use; International Only)
- Acute Inhalation Toxicity (End-Use; International Only)
- Toxicity - Bumblebee (Technical; International Only)
- Freshwater Fish Toxicity/Pathogenicity - Carp (Technical; Japan Only)
- Toxicity – Earthworm (Technical; International Only)
- Toxicity – Algal (Technical; International Only)

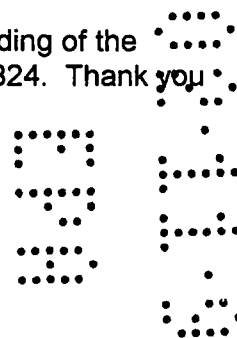
It is possible that we will conduct some or all of these studies and possibly other studies that are not listed.

I would appreciate receiving comments from you regarding our understanding of the requirements to register *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. Thank you again for your usual kind assistance.

Sincerely,



Edgar R. Butts, Ph.D.  
President and Chief Executive Officer



DETAILED LISTING OF DATA SUBMITTED AND REQUESTS FOR WAIVERS  
TO SUPPORT APPLICATION FOR REGISTRATION  
OF  
*BACILLUS SUBTILIS* VAR. *AMYLOLIQUEFACIENS* STRAIN FZB24  
February 8, 1999

PRODUCT CHEMISTRY

**151A-10      Product Identity and Disclosure of Ingredients**

Document 1    Product Identity and Disclosure of Ingredients – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. Data Requirement: 152A-10. Edgar R. Butts, Ph.D., Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 3, 1999. 35 Pages.

**151A-11      Beginning Materials and Manufacturing Process**

Document 2    Beginning Materials and Manufacturing Process – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. Data Requirement: 151A-11. Ulrich Korn, Ph.D. FZB Biotechnik GmbH, Glienicke Weg 185, D-12489 Berlin, GERMANY. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 5, 1999. 26 Pages.

**151A-12      Discussion of Formation of Unintentional Ingredients**

Document 3    Discussion of Formation of Unintentional Ingredients – *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24. Data Requirement: 151A-12. Dr. Ralph Freudenthal, Ph.D., Consultant – Toxicology and Regulatory Affairs, 8737 Estate Drive, West Palm Beach, FL 33411. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 21, 1999. 4 Pages.

**151A-13      Analysis of Samples**

Document 4    Lot Analysis of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24. Data Requirement: 151A-13 (885.1400). Bruce A. Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L03743 SN23. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 19 Pages.

**151A-15      Certification of Limits**

Document 5    Certification of Limits. Data Requirement: 151A-15. Edgar R. Butts, Ph.D., Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 5, 1999. 10 Pages.

**151A-16      Physical/Chemical Properties - Technical**

Document 6    Determination of Color, Physical State, Odor, pH and Density of *Bacillus subtilis* var. *amyloliquefaciens*. Data Requirement: 151A-16 (Color 830.6302, Physical State 830.6303, Odor 830.6304, pH 830.7000, Density 830.7300). Ronda Jacobs and Willard B. Nixon, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 10, 1998. 22 Pages.

**151A-16      Physical/Chemical Properties – “WDG” End-Use Product**

Document 7    Determination of Color, Physical State, Odor, pH and Density of *Bacillus subtilis* var. *amyloliquefaciens* “WDG” End-Use Product. Data Requirement: 151A-16 (Color 830.6302, Physical State 830.6303, Odor 830.6304, pH 830.7000, Density 830.7300). Ronda Jacobs and Willard B. Nixon, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 10, 1998. 20 Pages.

**151A-16      Physical/Chemical Properties – Corrosion Characteristics – “WDG” End-Use Product**

This study is underway and will be submitted as soon as complete.

## TOXICOLOGY

### 152A-10 Acute Oral Toxicity/Pathogenicity - Technical

Document 8 Toxicity/Pathogenicity Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, Following Acute Oral Challenge in Rats. Data Requirement: 152A-10 (885.3050). Kelly A. Harrington, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN2. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 123 Pages.

### 152A-10 Acute Oral Toxicity – “WDG” End-Use Product

Document 9 Acute Toxicity/Limit Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, WDG End Use Product, Following Acute Oral Challenge in Rats. Data Requirement: 152A-10 (870.1100). Bruce Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN8. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 29 Pages.

### 152A-11 Acute Dermal Toxicity/Pathogenicity - Technical

Document 10 Acute Dermal Toxicity/Pathology Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, in Rabbits. Data Requirement: 152A-11 (885.3100). John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN5. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 28 Pages.

**152A-11      Acute Dermal Toxicity/Pathogenicity – “WDG” End-Use Product**

Document 11 Acute Dermal Toxicity/Pathology Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, WDG End Use Product in Rabbits. Data Requirement: 152A-11 (885.3100). John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN10. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 28 Pages.

**152A-12      Acute Pulmonary Toxicity/Pathogenicity - Technical**

Document 12 Toxicity/Pathogenicity Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, Following Acute Intratracheal Challenge in Rats. Data Requirement: 152A-12 (885.3150). Kelly A. Harrington, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN3. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 133 Pages.

**152A-12      Acute Inhalation Toxicity – “WDG” End-Use Product**

This study is underway and will be submitted as soon as complete.

**152A-13      Acute Intravenous Toxicity/Pathogenicity - Technical**

Document 13 Toxicity/Pathogenicity Testing of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, Following Acute Intravenous Challenge in Rats. Data Requirement: 152A-13 (885.3200). Bruce A. Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN4. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 119 Pages.



**152A-14      Primary Eye Irritation - Technical**

Document 14 Primary Eye Irritation Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, in Rabbits. Data Requirement: 152A-14. John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN6. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 25 Pages.

**152A-14      Primary Eye Irritation – “WDG” End Use Product**

Document 15 Primary Eye Irritation Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, WDG End Use in Rabbits. Data Requirement: 152A-14. John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN11. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 23 Pages.

**152A-15      Hypersensitivity Incident Reporting**

Document 16 Hypersensitivity Incident Reporting. Data Requirement: 152A-15. Edgar R. Butts, Ph.D., Taensa, Inc., 26 Sherman Court, P.O. Box 764, Fairfield, CT 06430. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 3, 1999. \_\_\_\_ Pages.

**152A      Hypersensitivity Testing - Technical**

Document 17 Dermal Sensitization Study of *Bacillus subtilis* var. *amyloliquefaciens*, Strain FZB24, in Guinea Pigs Using the Buehler Method. Data Requirement: 152A (870.2600). John Findlay, B.S., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN7. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 27 Pages.



**152A      Potential Health Effects of *Bacillus subtilis* var. *amyloliquefaciens*  
Strain FZB24 – A Review of the Literature**

Document 18 Potential Health Effects of *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24 – A Review of the Literature. Data Requirement: 152A. Ralph I. Freudenthal, Ph.D., Consultant – Toxicology and Regulatory Affairs, 8737 Estate Drive, West Palm Beach, FL 33411. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: February 4, 1999. 8 Pages.

**152A      Growth Parameters of *Bacillus subtilis* var. *amyloliquefaciens*.  
Strain FZB24 at Various Temperatures**

Document 19 Growth Parameters of *Bacillus subtilis* var. *amyloliquefaciens*. Strain FZB24, at Various Temperatures. Data Requirement: 152A. Bruce A. Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN25. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 1999. 14 Pages.

**152A      Sensitivity of Detection**

Document 20 Sensitivity of Detection of *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24, for Toxicity/Pathogenicity Testing in Rats. Data Requirement: 152A. Bruce A. Gingras, Ph.D., IIT Research Institute, Life Sciences Operation, 10 West 35<sup>th</sup> Street, Chicago, Illinois 60616-3799. Laboratory Project Identity: L08743 SN1. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 1998. 33 Pages.

## ECOLOGICAL EFFECTS

### 154A-16 Avian Acute Oral Toxicity/Pathogenicity - Technical

Document 21 *Bacillus subtilis* var. *amyloliquefaciens* - An Avian Oral Pathogenicity and Toxicity Study in the Northern Bobwhite. Data Requirement: 154A-16 (885.4050). James W. Foster, Jennie Grimes and Joann Beavers, Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Project Number: 495-101. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 21, 1998. 28 Pages.

### 154A-19 Freshwater Invertebrate Toxicity/Pathogenicity - Technical

Document 22 *Bacillus subtilis* var. *amyloliquefaciens* - A 21-Day Life-Cycle Toxicity and Pathogenicity Test with the Cladoceran (*Daphnia magna*). Data Requirement: 154A-19 (885.4240). Kurt R. Drott and Henry O. Krueger, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Project Number: 495A-102. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 6, 1999. 36 Pages.

### 154A-20 Freshwater Fish Toxicity/Pathogenicity - Technical

Document 23 *Bacillus subtilis* var. *amyloliquefaciens* - A Five-Concentration Toxicity and Pathogenicity Test with Rainbow Trout (*Oncorhynchus mykiss*). Data Requirement: 154A-20 (885.4200). Kurt R. Drott and Henry O. Krueger, Ph.D., Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Project Number: 495A-101. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: January 6, 1999. 30 Pages.

### 154A-21 Marine/Estuarine Toxicity/Pathogenicity

Waivers are requested because of low toxicity of *Bacillus subtilis* var. *amyloliquefaciens* on aquatic species. Please see documents 22 and 23. There are no reports in the literature of *Bacillus subtilis* being insecticidal.

**154A-22      Non-Target Plant Studies**

Waivers are requested because of *Bacillus subtilis* var. *amyloliquefaciens* has been tested on many different crops and plants without phytotoxicity. To the contrary, *Bacillus subtilis* var. *amyloliquefaciens* will be used as a plant growth enhancer.

**154A-23      Non-Target Insect Toxicity/Pathogenicity – Green Lacewing  
154A-23      Non-Target Insect Toxicity/Pathogenicity – Parasitic Wasp  
154A-23      Non-Target Insect Toxicity/Pathogenicity – Ladybug Beetle**

Waivers are requested because of low toxicity of *Bacillus subtilis* var. *amyloliquefaciens* on insect species. Please see documents 22, 24, and 25. There are no reports in the literature of *Bacillus subtilis* being insecticidal.

**154A-24      Larval Honeybee Toxicity/Pathogenicity - Technical**

Document 24 Evaluation of the Dietary Effect(s) of *Bacillus subtilis* var. *amyloliquefaciens* on Honey Bee Larvae (*Apis mellifera* L.). Data Requirement: 154A-24 (885.4380). Victor L. Maggi, M.S., California Agricultural Research, Inc., 4141 N. Vineland, Kerman, CA 93630. Study Laboratory Number: CAR 167-98. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 18, 1998. 52 Pages.

**154A-24      Adult Honeybee Toxicity/Pathogenicity - Technical**

Document 25 Evaluation of the Dietary Effect(s) of *Bacillus subtilis* var. *amyloliquefaciens* on Adult Honey Bees (*Apis mellifera* L.). Data Requirement: 154A-24 (885.4380). Victor L. Maggi, M.S., California Agricultural Research, Inc., 4141 N. Vineland, Kerman, CA 93630. Study Laboratory Number: CAR 167-98. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 18, 1998. 96 Pages.

**154A      Earthworm Toxicity - Technical**

Document 26 *Bacillus subtilis* var. *amyloliquefaciens* Strain FZB24: An Acute Toxicity Study with the Earthworm in an Artificial Soil Substrate. Data Requirement: 154A (OECD Guideline 207). Kimberly A. Hoxter, Susan J. Palmer, and Henry O. Krueger, Wildlife International Ltd., 8598 Commerce Drive, Easton, MD 21601. Unpublished study conducted for and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: December 21, 1998. 21 Pages.

154A

**Algal Toxicity - Technical**

Document 27 Algae Growth Inhibition Test – Test Article: *Bacillus subtilis* Strain FZB24. Data Requirement: 154A (OECD Guideline 201). Dr. M. Jahnke, IBR Forschungs GmbH, Südkampen 31, 29664 Walsrode, GERMANY. Unpublished study conducted for FZB Biotechnik, Glienicker Weg 185, 12489 Berlin, GERMANY and submitted by Taensa, Inc., P.O. Box 764, Fairfield, CT 06430. Completion Date: August 29, 1994. 36 Pages.

# REGISTRATION JACKET INTRA-TRANSFER REQUEST

(PLEASE FILL OUT FORM COMPLETELY)

TRANSFER FILE TO: Janet Anderson  
PM 92 PHONE: \_\_\_\_\_

REASON FOR TRANSFER: ☐ RSB CHEMISTRY REVIEW ☐ CODING (SIG)  
☐ ACTION COMPLETED ☐ PRECAUTIONARY LABEL REVIEW  
☐ WITHDRAW PENDING APPLICATION  
☐ OTHER \_\_\_\_\_

TRANSFERRED FROM: Karen Garner (SIG) PHONE: 305-5175  
DATE OF REQUEST: 2/1/2000 PM TEAM: \_\_\_\_\_  
(If Applicable)

## REGISTRATION NUMBER(S) OF JACKET(S) TO BE TRANSFERRED

(PLEASE INDICATE VOLUME NUMBER, IF APPLICABLE)

REGISTRATION#	COMMENTS	LOCATION	OTHER INFORMATION
<u>72098 - 6</u>	_____	_____	_____
<u>72098 - 5</u>	_____	_____	_____
_____	_____	_____	_____
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_____	_____	_____	_____

SPECIAL COMMENTS:

FOR FILE ROOM STAFF USE

NOTIFY REQUESTOR:

DATE

TIME

INITIALS



# PPIS Deficiency Notice

PM NUMBER: 92

REGISTRATION NUMBER: 72098 - 6

Data Analyst: James Hinkle

Date Processed: 2 / 1 / 00

This jacket has been found to be deficient according to established EPA data processing guidelines for the following reasons:

1. Current accepted label dated 1 / 20 / 2000  
☐ Is missing from the jacket. ☐ Is missing acceptance stamp.  
☒ Acceptance stamp is missing date and/or registration number.  
☐ Is missing the following information: \_\_\_\_\_
2. Acceptance letter dated \_\_\_\_\_ and associated label are inconsistent concerning:  
☐ Acceptance date. ☐ Product name. ☐ Registration number.
3. Comments letter associated with label dated \_\_\_\_\_ / \_\_\_\_\_ is missing from the jacket.
4. Accepted (Basic / Alternate) CSF dated \_\_\_\_\_ / \_\_\_\_\_  
☐ Is missing from the jacket. ☐ Is misfiled or has wrong registration number.  
☐ Sole active ingredient source product \_\_\_\_\_ has been cancelled.
5. ☐ Active and inert chemical percentages do not equal 100%.
6. ☐ Other information missing inconsistent within the jacket. See below for details.

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